Module 2
Site Characterization

Contents

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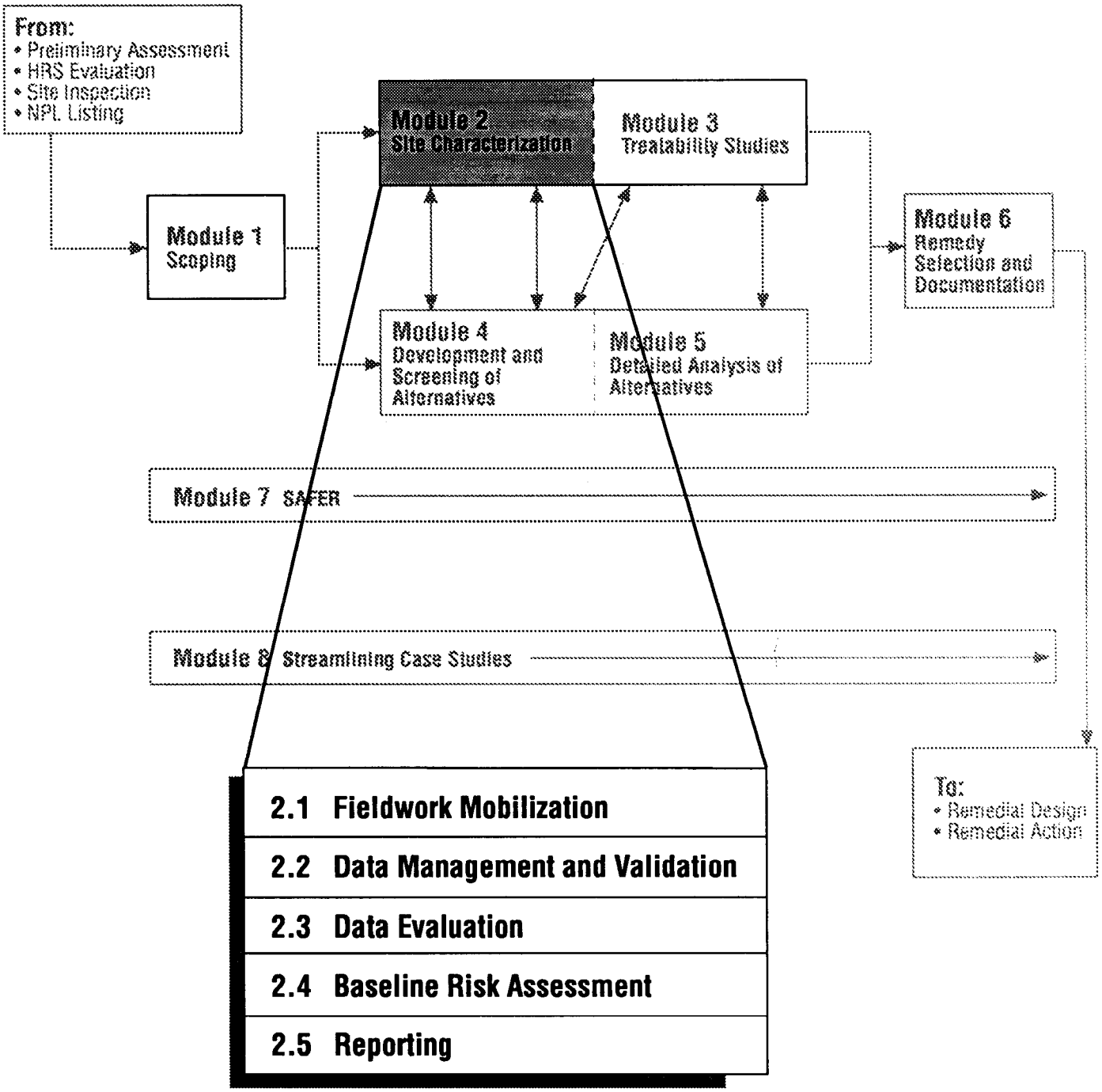

Module 2
Site Characterization

Background

In Section 300.430(d) of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), the Department of Energy (DOE) as the lead agency is charged with characterizing the site and, as appropriate, conducting field investigations and a baseline risk assessment. The NCP (Sections 300.430(d))(2), (3), and (4) identifies specific objectives of site characterization, which include the following:

- Characterizing the nature and threat posed by hazardous substances and materials; gathering data necessary to assess the extent to which the release poses a threat to human health or the environment; and supporting the analysis and design of potential response actions by assessing the following factors
  - Physical characteristics of the site
  - Chemical characteristics and contamination of air, surface water, and groundwater
  - Characteristics of wastes including quantities, concentration, toxicity, propensity to bioaccumulate, persistence, and mobility
  - Known and potential transport pathways through environmental media
  - Known and potential exposure routes
  - Other factors, such as sensitive populations, that pertain to the characterization of the site or support the analysis of potential Remedial Action (RA) alternatives
- Working with the Environmental Protection Agency (EPA) and the state to identify potential applicable or relevant and appropriate requirements (ARARs) related to the location of the site and contaminants at the site. Other pertinent advisory criteria or guidance may be identified, as appropriate.
- Conducting a site-specific baseline risk assessment to characterize the current and potential threats to human health and the environment that may be posed by contaminants.

The main purposes of site characterization, as described in Module 2, are as follows:

(1) Implement the remedial investigation that was planned in detail during the scoping phase. This includes identifying and resolving fieldwork mobilization issues that could cause schedule delays resulting in unnecessary costs. These issues include field logistics, laboratory logistics, and Investigation-Derived Waste (IDW) management.

(2) Evaluate the results of the remedial investigation and revise the conceptual model to reflect the new understanding of how the site works, the probable conditions, and uncertainties about the probable conditions.

(3) Complete the baseline risk assessment, using the information gained from the remedial investigation.


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Organization

Module 2 is divided into five submodules

2.1 Fieldwork Mobilization
2.2 Data Management and Validation
2.3 Data Evaluation
2.4 Baseline Risk Assessment
2.5 Reporting

Documents

Informal and formal reports are used to document and communicate results of activities during site characterization. The documents that should be developed during site characterization include the following:

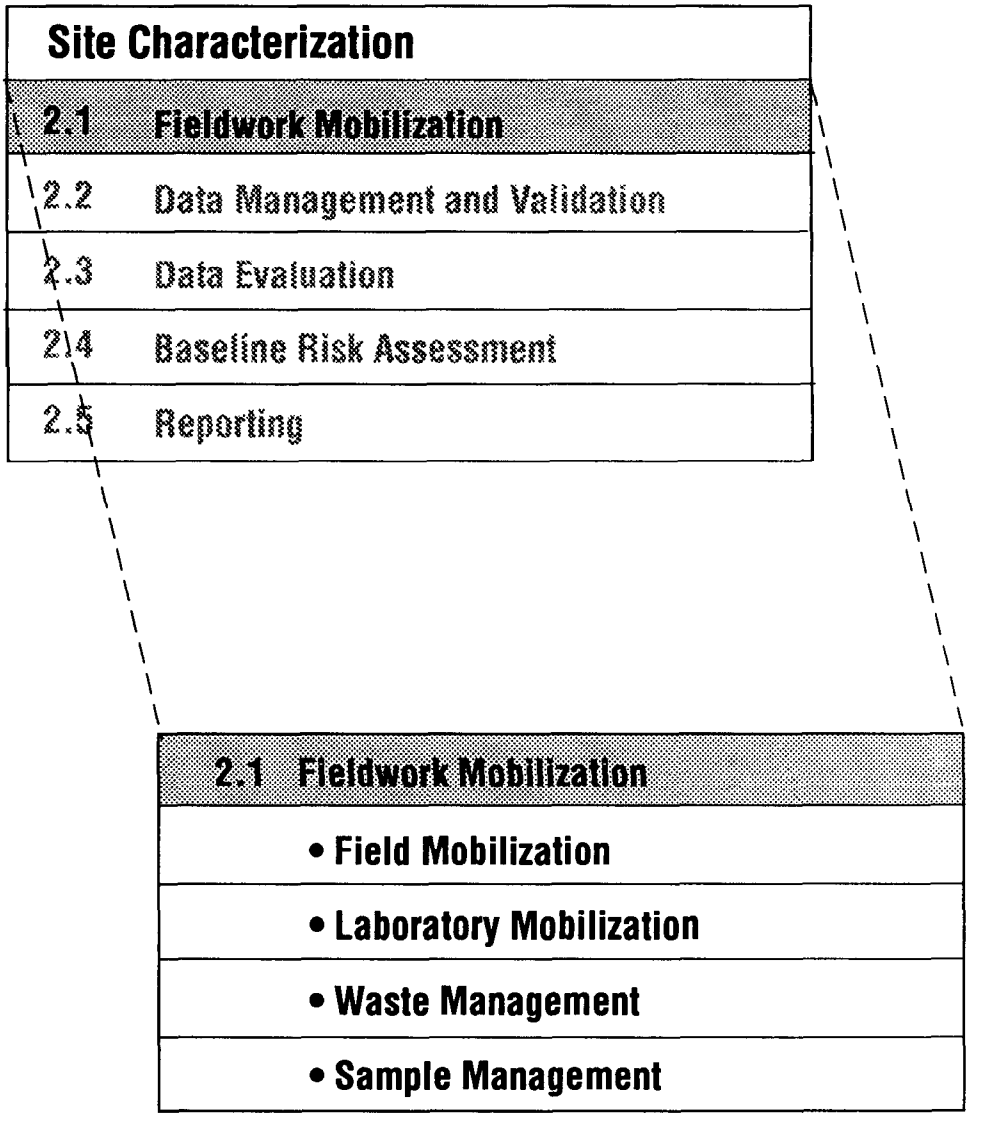
(1) Site Characterization Summary Report

(2) Baseline Risk Assessment Report

(3) Remedial Investigation Report

(4) Other technical memoranda summarizing results as needed

Submodule 2.1 Fieldwork Mobilization



Submodule 2.1 Fieldwork Mobilization

Background

Fieldwork can proceed on schedule by identifying and resolving mobilization issues. Significant time delays and cost overruns will result if these issues are not addressed well in advance of beginning fieldwork.

Organization

Submodule 2.1 discusses the following:

- Field mobilization
- Laboratory mobilization
- Waste management
- Sample management

In addition, more detailed information is provided in the following notes:

- Note A–Checklist on Field Mobilization Issues
- Note B–Sample Management

Sources

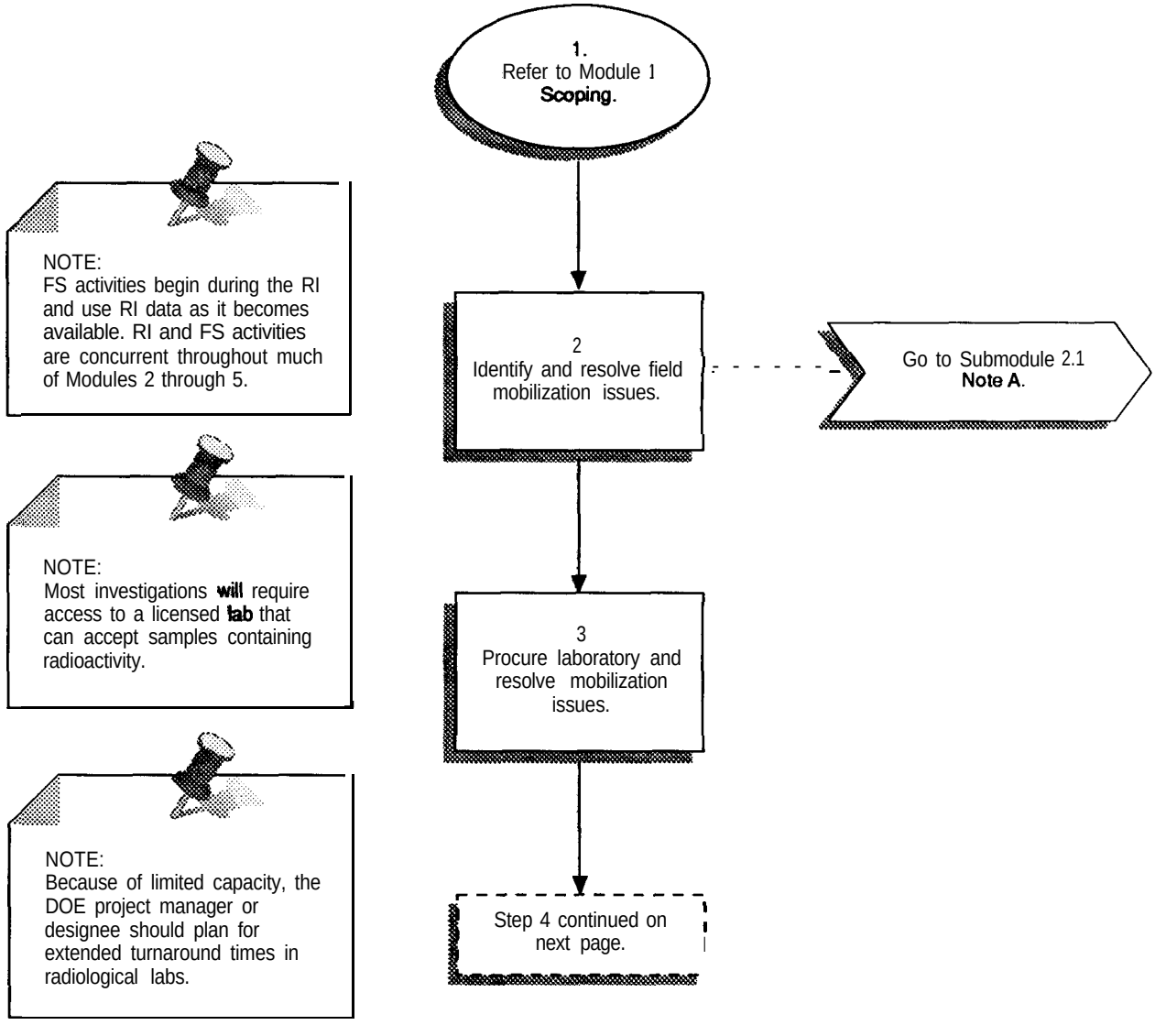
1. U.S. EPA, September 1987, *A Compendium of Superfund Field Operations Methods*, EPA/540/P-87/001, OSWER Directive 9355.0-14.

2. U.S. EPA, October 1988, *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA*, Interim Final, EPA/540/G89/004, OSWER Directive 9356.3-01.

3. U.S. EPA, December 1989, *Risk Assessment Guidance for Superfund, Volume 1–Human Health Evaluation Manual, Part A*, Interim Final, EPA/540/1-89/002.

4. U.S. EPA, April 1992, *Guide to Management of Investigation-Derived Wastes*, OSWER Directive 9345.3-03FS.

Submodule 2.1 Fieldwork Mobilization



Step 1. Refer to Module 1, Scoping the RI/FS.

Step 2. **Identify and resolve field mobilization issues.** Prior to beginning fieldwork, the DOE operable unit (OU) manager or designee will need to resolve several mobilization issues that are not typically addressed in a Remedial Investigation/Feasibility Study (RI/FS) work plan. The following major issues often are difficult to accommodate at a DOE site: (1) procurement; (2) organization and management of the fieldwork; (3) staff training; (4) quality assurance (QA) oversight; (5) site access and security; (6) permits; (7) health and safety of workers; and (8) communications during fieldwork. These issues generally are internal to DOE and its contractors and often do not involve stakeholders. Agreement among extended project team members is critical for consistent implementation of RI/FS activities. Resolution of these issues should be documented in internal memoranda, operating procedures, or other appropriate documents. See Submodule 2.1, Note A, for further information on these issues.

Step 3. **Procure laboratory and resolve mobilization issues.** The site may have existing access to fixed laboratories (onsite or offsite) or this capacity may need to be procured. In either situation, project-specific requirements will need to be identified and the selected laboratory will need to meet these requirements. Evaluation of proposed laboratories should be based on whether the laboratory:

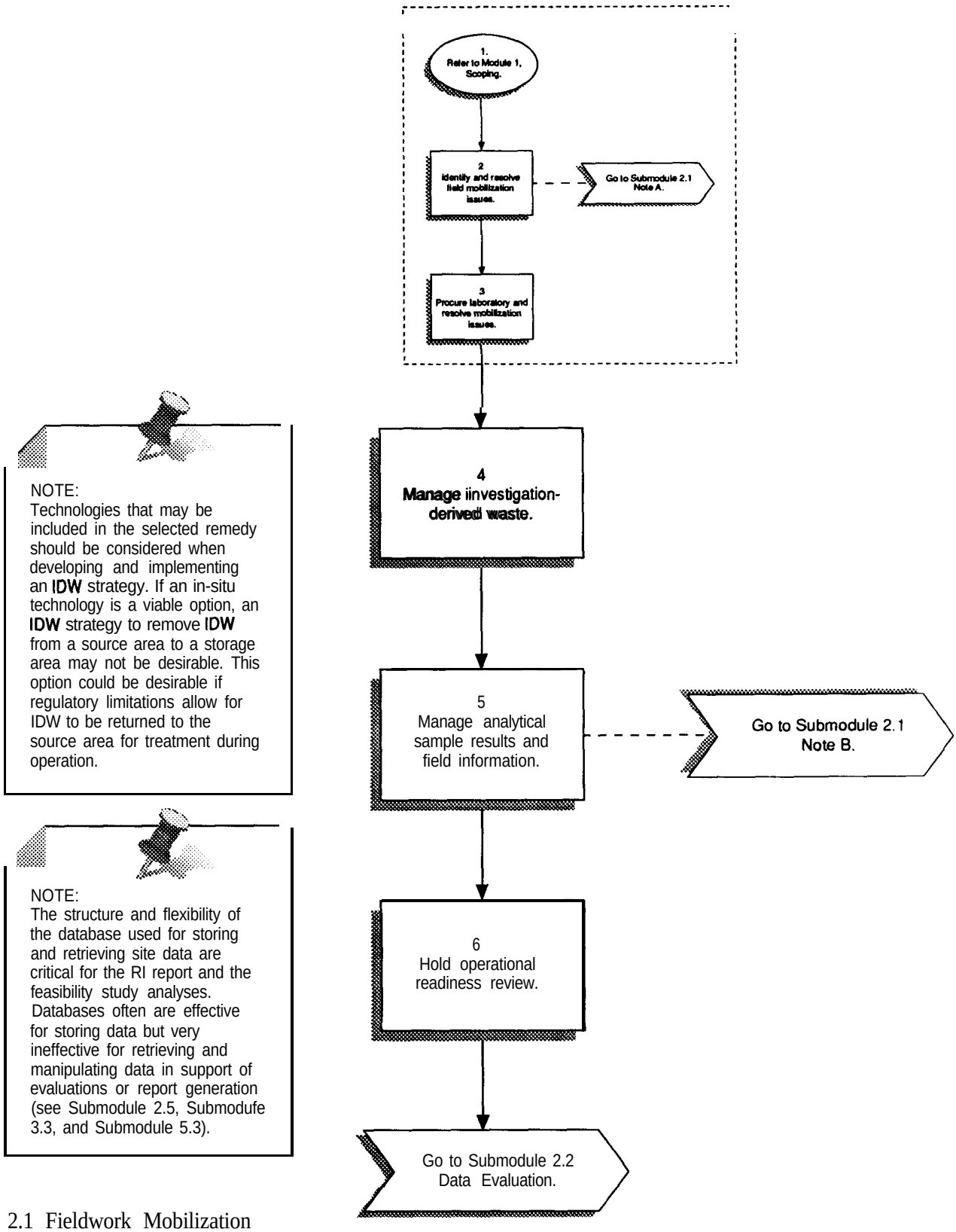
- Has been approved and audited by the management and operating (M&O) contractor or by DOE.
- Has been licensed by the Nuclear Regulatory Commission (NRC) for acceptance of low-level radiation-contaminated samples.
- Has implemented an ongoing QA program.
- Participates in EPA's Performance Evaluation Program.
- Has the capacity and turnaround times to handle the proposed sampling effort.

Two types of laboratories will be required during fieldwork: (1) Field Support Laboratory (FSL) or Close Support Laboratory (CSL) and (2) fixed laboratories.

An FSL will be needed to screen (for radioactivity) any samples that leave the site. FSLs also can be used to provide QA Level I and II sample analyses that can be used to make characterization decisions and to confirm decontamination activities. FSLs often are trailer-based facilities that can be moved to the appropriate site location. Site utilities and related permits (such as air discharge) should be coordinated through appropriate site personnel. Specialized equipment may need to be procured for installation in the FSL.

The facility design for decontamination of equipment and vehicles should be identified in the work planning phase. The decontamination area should be designed to support activities outlined in the Waste Management Plan (see Submodule 1.5). Permits and procurement for the decontamination facility will need to be coordinated with the appropriate plant or facility personnel.

Submodule 2.1 Fieldwork Mobilization (cont.)



The project-required methods, detection limits, special analytical services and associated procedures, and deliverables consistent with the data quality objectives (DQOs) that are outlined in the Quality Assurance Project Plan (QAPP) should be finalized in the contract with the selected laboratory. Penalties should be negotiated for missed holding times or deliverable times.

Managers should consider whether electronic data transfer from the laboratory is compatible with software design. If electronic data transfer is desired, format and quality control (QC) criteria should be specified. Such a requirement should be detailed (as an appendix to the work plan) in the Data Management Plan.

Step 4. **Manage Investigation-Derived Waste (IDW).** Waste management issues are a significant responsibility during RI activities. The IDW Management Plan, an appendix to the work plan, must be followed during the RI. Mobilization issues for implementing this plan often include the following:

- Availability of required materials (e.g., containers)
- Availability of and access to required storage space
- Transportation of IDW (e.g., compliance with health physics procedures)
- Procedures to maintain IDW during storage in compliance with regulatory requirements [e.g., Resource Conservation and Recovery Act (RCRA) generator and storage requirements]
- Scheduling with facilities that will manage IDW [e.g., onsite or offsite treatment, storage, or disposal (TSD) facilities]
- Establishing protocols for sampling and analyzing IDW for subsequent waste management decisions.

An overview of requirements for managing IDW is found in the *Guide to Management of Investigation-Derived Wastes* (DOE, 1992).

Step 5. **Manage analytical sample results and field information.** Every sample must have an auditable history of how and where it was collected, how it was handled after collection, how it was transported to the laboratory and analyzed, and how the data generated from the analysis was validated and managed. Such procedures are identified in the work plan. Onsite managers must ensure that all staff are trained in these procedures and that the procedures are followed. During mobilization, site managers should ensure that the systems will work. If an auditable trail is not maintained for each sample, the usability of the sample is impaired (see Submodule 2.1, Note B).

Step 6. **Hold operational readiness review.** An operational readiness review meeting is essential prior to mobilization. The DOE project manager or designee is responsible for conducting the meeting. All premobilization issues addressed in this submodule must be reviewed for a final time to ensure that all appropriate arrangements are made and that the field teams are actually ready to begin the field effort. These issues may include notifying stakeholders when fieldwork will begin. Meeting minutes should be prepared and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distributed by the DOE project manager or designee. The minutes should include a final list of remaining items to be completed as well as responsibility for specific assignments.


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Note A. **Checklist on Field Mobilization Issues.** Many mobilization issues need to be resolved before initiation of fieldwork. This checklist provides identification and description of major field mobilization issues that will be encountered during RI/FS projects at DOE facilities.

- **Procurement**: Contractors and equipment should be procured if required for work plan implementation. If a procurement vehicle exists, acquisition time for the contractors and equipment should take no longer than 2 to 4 months. If a procurement vehicle needs to be established, the time to procure contractors could take significantly longer (many months).

- **Organization and Management**: Effectiveness of the field team organization will impact the ability to manage cost and schedule requirements. Fieldwork should be organized in a structure similar to the tasks identified in the RI/FS work plan. In order to complete the work in a timely manner, multiple-task teams will probably be in the field simultaneously. A contractor field team leader should be identified for effective management of multiple-task teams. Communication is more effective if the multiple-task teams communicate with the contractor OU project manager through a single field team leader. The field team leader is the most critical position at this stage because of day-to-day responsibility for fieldwork. Other OU projects can provide insight about establishing an effective organization and management structure. In addition, sitewide management plans or compliance agreements may have specific requirements for organization and management of fieldwork.

- **Training**: The two primary types of training relevant to fieldwork are (1) mandatory training requirements for compliance with regulations [e.g., Occupational Safety and Health Administration (OSHA) 40-hour training, appropriate radiological protection training]; and (2) training required to adequately and responsibly perform job functions (e.g., equipment operation and calibration, site-specific emergency response procedures). Refer to appropriate regulations to identify required regulatory training (e.g., RCRA, NCP, OSHA) and internal facility procedures and work plan sampling procedures for job-specific training requirements.

- **QA Oversight**: QA includes implementing fieldwork in a manner consistent with the work plan and other established QA procedures (e.g., DOE Order 5700.6C). Fieldwork audits will be conducted as a part of QA oversight. The QAPP in the work plan should identify QA oversight procedures. Facility QAPP plans may also have field audit procedure requirements such as frequency of audits.

- **Site Access and Security**: Site access includes physical access required to implement the work plan (e.g., drilling access, weather conditions). Access should be obtained through appropriate facility personnel, which may include multiple landlord issues. This may require significant time to obtain access and should be sought as soon as the need is identified (e.g., during scoping) or to meet special conditions (e.g., coordination with ongoing operations). If security clearances are necessary for contractor personnel, sufficient


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processing time should be anticipated. A DOE "L" clearance can take up to a year to obtain. An alternative to obtaining security clearances is to identify and include facility escorts on the field teams.

- **Health and Safety**: DOE places paramount importance on worker health and safety, which is critical to implementation of all work plan activities. Oversight reports have suggested that health and safety issues have not received sufficient attention during fieldwork. OU project managers must consider known conditions, uncertainties, and physical and work-related hazards in cost and schedule evaluations. OU project managers are responsible for recognizing and evaluating health and safety issues as long as fieldwork is being conducted. Insight to project-specific health and safety issues is provided in work plan and facility-wide Health and Safety Plan (HSP).

- **Permits**: Delays will result if appropriate internal requirements for implementing fieldwork activities are not met in advance. Internal requirements may include excavation and National Environmental Policy Act (NEPA) categorical exclusions, which should be coordinated through the appropriate facility personnel.

- **Communications**: Early identification and resolution of problems are crucial to maintaining the consensus-building process begun during Scoping (see Module 1); effective communications are essential. Three main levels of communications should be established during fieldwork: frequent internal communications between DOE and contractors; regular communication among extended project team members; and stakeholder communication as agreed to during Scoping (see Module 1).


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Note B. **Sample Management.** To achieve technically and legally defensible data, an audit trail should be traceable from data collection through archiving. Field logs should be maintained as the primary record of daily field activities and should include documentation of any modifications to outlined procedures or protocols pursuant to the work plan, health and safety plan, and field sampling plan. Field measurements and observations should be recorded directly into project logbooks.

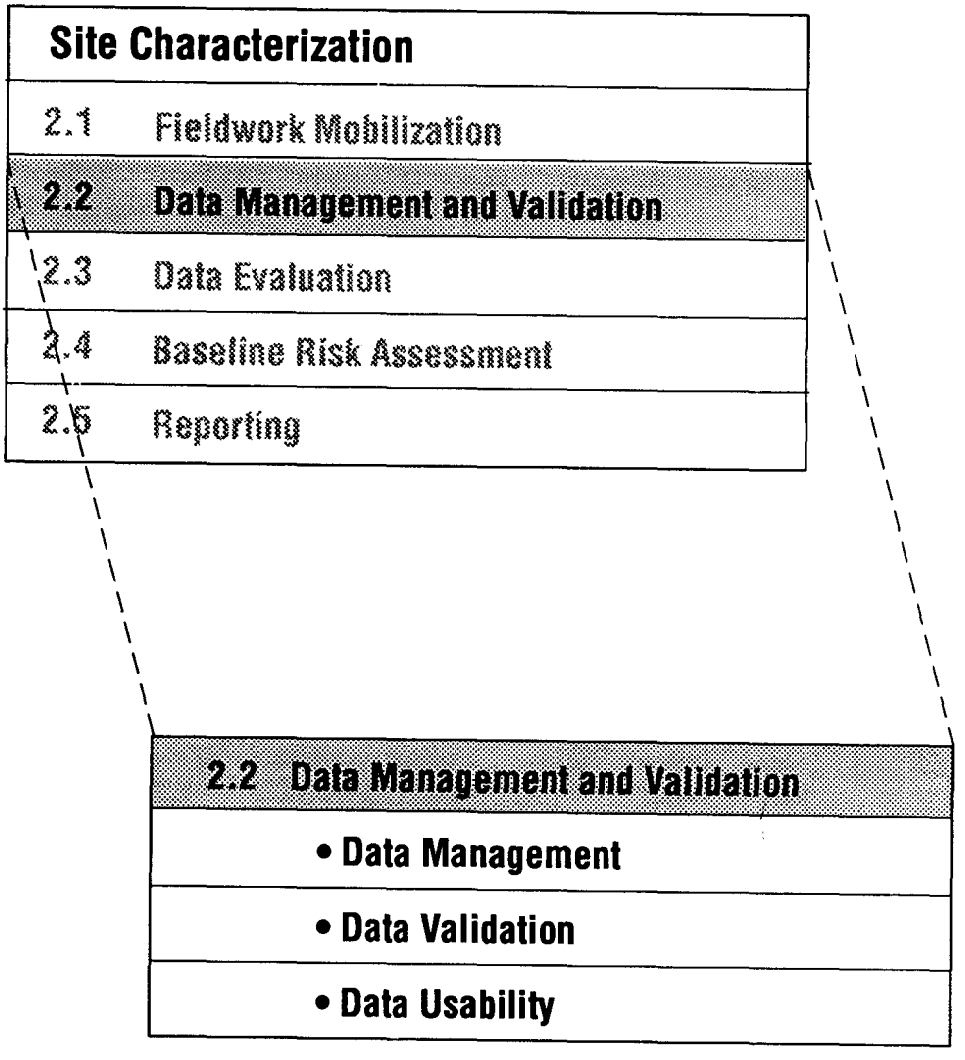
Samples collected during the RI should be tracked from the field to the FSL, to subsequent laboratories for analysis, and through interim storage or disposal of sample residuals using standardized chain-of-custody forms. Sample results should also be tracked from laboratories through the validation process and input to the data management system. Information such as date, time, sample type, media, sample number, and sample activities can be entered in an electronic sample tracking database to aid in the tracking process. Project logbooks are an important and often required method of documenting fieldwork. Examples of field measurement entries in project logbooks include value of field parameters (pH, conductivity, temperature); soil characteristics; field procedures; sample number; designations; and health and safety monitoring results. Health and safety observations and/or incidences and general descriptions of daily activities are typically included in a daily log. Any unusual occurrences or discrepancies should be recorded in these logs for use in determining possible cause for data anomalies discovered during data evaluation. Data must be recorded directly and legibly into field logbooks, with entries signed and dated. Changes made to original notes should not obliterate the original information and should be initialed and dated. Standard format information sheets should be used whenever appropriate and should be retained in project files.

Documentation involved in maintaining field sample inventories and proper chain-of-custody records may include the following:

- Sample identification matrix
- Sample tag
- Traffic report
- High hazard traffic report
- Sample packing list
- Chain-of-custody form
- Notice of transmittal
- Receipt for sample form
- Shipping airbill

Additional information for each of these items, along with instructions for their completion, can be found in Section 6.2 of *Compendium of Superfund Field Operations Methods* (EPA, 1987). Further reference in this module will be to the *Compendium*.

Submodule 2.2 Data Management and Validation



Submodule 2.2 Data Management and Validation

Background

Data management and validation determine the quality and usability of the data. Use of quality data is essential to making defensible remedial decisions.

Organization

Submodule 2.2 discusses the following:

- Data management
- Data validation
- Data usability

Sources

1. U.S. EPA, 1988, *Laboratory Data Validation Functional Guidelines for Evaluating Organics Analysis*, Draft, EPA/540/2-88/503.

2. U.S. EPA, 1988, *Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analysis*, Draft.

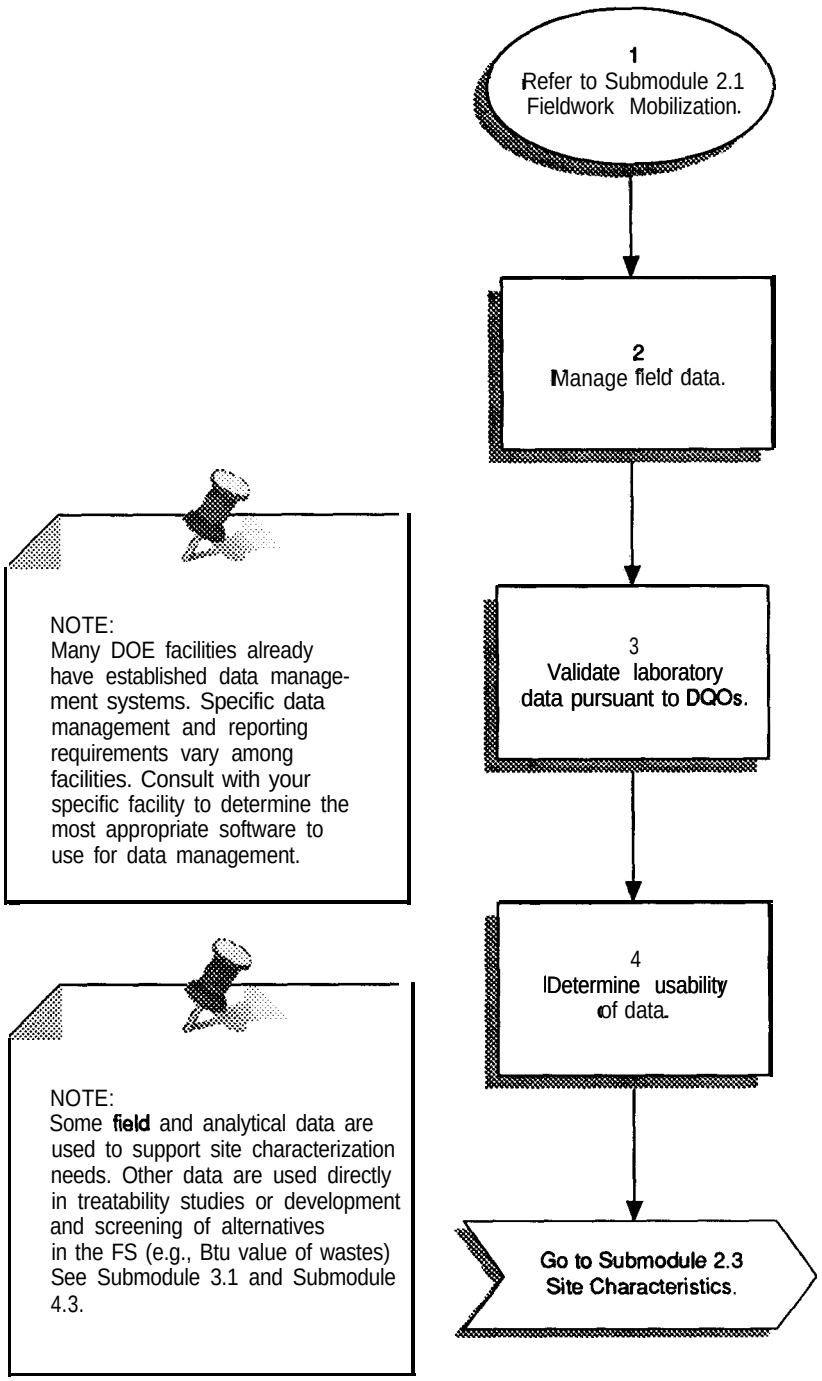
3. U.S. EPA, October 1988, *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA*, Interim Final, EPA/540/G89/004, OSWER Directive 9356.3-01.

4. U.S. EPA, December 1989, *Risk Assessment Guidance for Superfund, Volume 1. Human Health Evaluation Manual (Part A)*, Interim Final, EPA/540/1-89/002.

5. U.S. EPA, April 1992, *Guidance for Data Useability in Risk Assessment (Part A)*, OSWER Directive 9285.7-09A.

6. U.S. EPA, May 1992, *Guidance for Data Useability in Risk Assessment (Part B)*, OSWER Directive 9285.7-09B.

Submodule 2.2 Data **Management** and Validation



Step 1. Refer to Submodule 2.1, Field Mobilization.

Step 2. **Manage field data.** A management system is required for field-collected data (e.g., water level measurements), chain-of-custody data, analytical results, and QA/quality control (QC) results. An electronic system is required because of data volume and frequency of uses. Some DOE facilities have databases that are required for use; some sites will have to develop new systems. Data users should have major influence in database design. If an existing database is to be used, data/sample collection procedures, sample tracking procedures, and QA/QC procedures and documentation must be tailored to the system. Additional QC procedures for data entry or transfer must be developed in the work planning phase to prevent the introduction of errors and loss or misinterpretation of data.

A DOE project manager or designee should be familiar with the following data management system issues: (1) system capability to handle all data types that will be collected (e.g., ability to store and track radiological QC qualifiers); (2) ability to access and track required information in an easy and flexible manner, including ability to transfer information to other software systems; and (3) ability to share data between OUs (i.e., likely a single sitewide system rather than a series of individual OU custom systems). These issues have not always been handled well at DOE sites, resulting in significant time and schedule impacts.

Step 3. **Validate laboratory data pursuant to DQOs.** When analytical data are received from the laboratories, analysis methods and analytical performance are evaluated for conformance with DQOs specified in contractual requirements and established criteria in the QAPP. Chemical validation, if required by the QAPP, must be conducted in accordance with the most recent version of EPA's *Laboratory Data Validation Functional Guidelines for Evaluating Organics Analysis* (EPA, 1988) and *Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analysis* (EPA, 1988).

Neither EPA nor DOE have established radiological data validation procedures. Project-specific procedures developed to date frequently follow general requirements of Contract Laboratory Program (CLP) protocol developed for chemical validation procedures. This protocol may not be appropriate for radiological data. DOE and EPA are reviewing radiological data validation procedures in an effort to develop a standardized approach.

Data validation qualifiers and codes are attached to the data by the laboratories that conduct the analyses or by persons who perform the data validation. These qualifiers pertain to QA/QC issues and indicate the data quality and how it can be used to support RI/FS decisions. When making such decisions, data users must apply the data appropriately. For example, data qualified as "R" (rejected) cannot be used in a risk assessment.

Step 4. **Determine usability of data.** Evaluation of data quality for established project DQOs is performed to assess uncertainties about the usability of the data for interpretation, statistical analysis, and decisionmaking for risk management and RAs. This evaluation may result in reanalysis of some samples, the use of estimated concentrations, and/or the elimination of certain chemicals from further consideration. Decisions about the usability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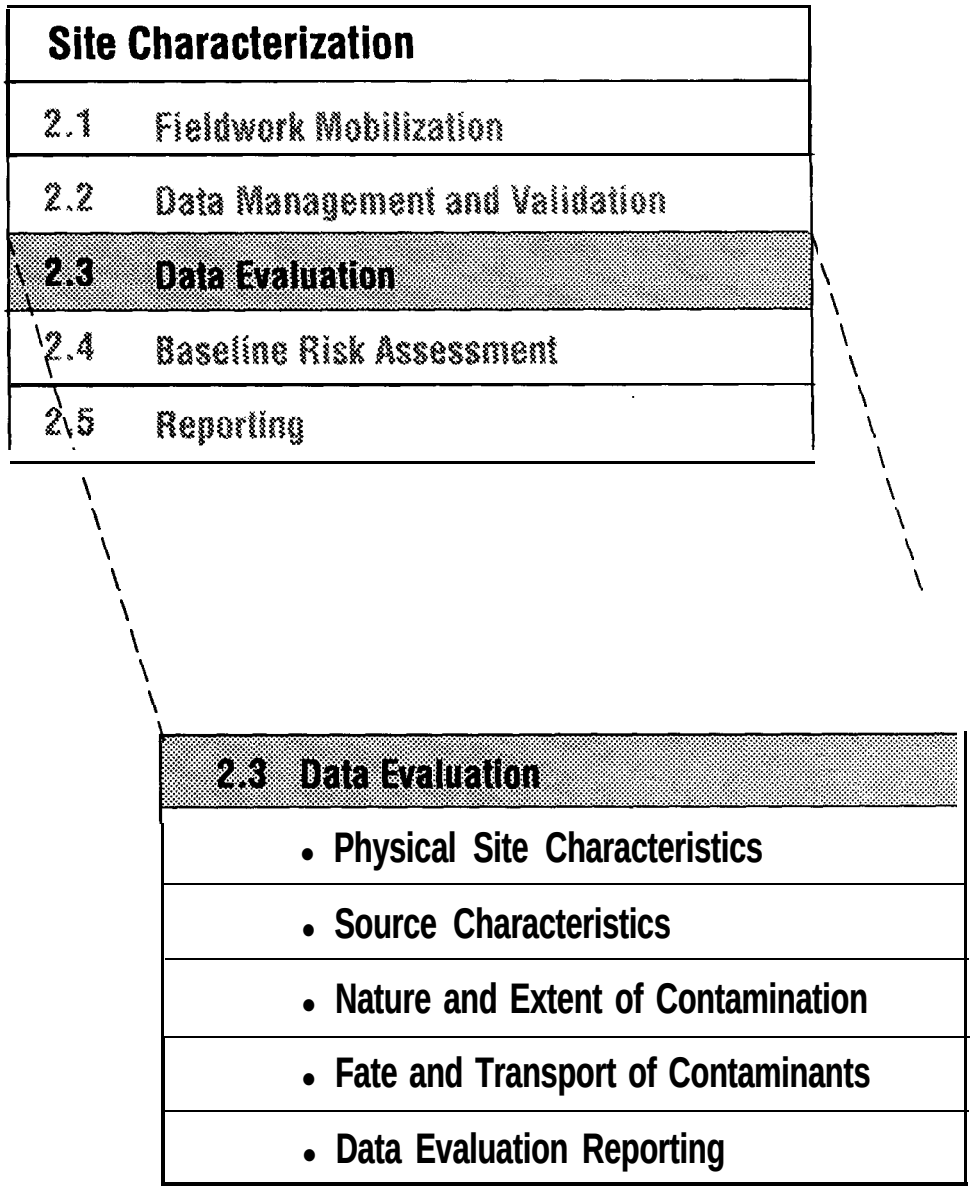
of questionable data should be made with involvement of the appropriate members of the extended project team. A technical memorandum that summarizes the results of the validation and explains any significant problems can be very effective for eliciting stakeholder input.

Submodule 2.3 Data Evaluation



Submodule 2.3 Data Evaluation

Background

The data are evaluated to confirm the conceptual site model to the degree needed to perform baseline risk assessment, ARARs evaluation, and development and evaluation of remedial alternatives. Four parts of the conceptual site model generally require data collection and evaluation: physical site characteristics, source characteristics, nature and extent, and fate and transport of contaminants.

During scoping, data gaps were identified and grouped into two categories. Data gaps that represented uncertainties about the site that can be managed during remediation were categorized as acceptable uncertainties. Data gaps that required data collection were categorized as data needs. Following data collection, data needs are evaluated in three steps: (1) Review and present data; (2) Confirm and refine the conceptual site model, including probable conditions and reasonable deviations; and (3) Reevaluate DQOs to determine whether data needs are met or additional data needs are identified.

Organization

Submodule 2.3 discusses the following:

- Physical site characteristics
- Source characteristics
- Nature and extent of contamination
- Fate and transport of contaminants
- Data evaluation reporting

In addition, more detailed information is provided in the following notes:

- Note A–Physical Characteristics
- Note B–Source Characteristics
- Note C–Nature and Extent of Contamination
- Note D–Fate and Transport of Contamination

Sources

1. U.S. EPA, December 1987, *A Compendium of Superfund Field Operations Methods*, OSWER Directive 9355.0-14, EPA/540/P-87/001.

2. U.S. EPA, March 1987, *Data Quality Objectives for Remedial Response Activities*, EPA/540/G-87/003, OSWER Directive 9355.0-7B.

3. U.S. EPA, April 1988, *Superfund Exposure Assessment Manual*, EPA/540/1-88/001, OSWER Directive 9285.5-1.

4. U.S. EPA, August 1988, *Draft Guidance on Remedial Actions for Contaminated Groundwater at Superfund Sites*, OSWER Directive 9283.1-2.

5. U.S. EPA, October 1988, *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA*, Interim Final, EPA/540/G-89/004, OSWER Directive 9355.3-01.

6. U.S. EPA, December 1989, *Risk Assessment Guidance for Superfund, Volume 1–Human Health Evaluation Manual*, Part A, Interim Final, EPA/540/1-89/002.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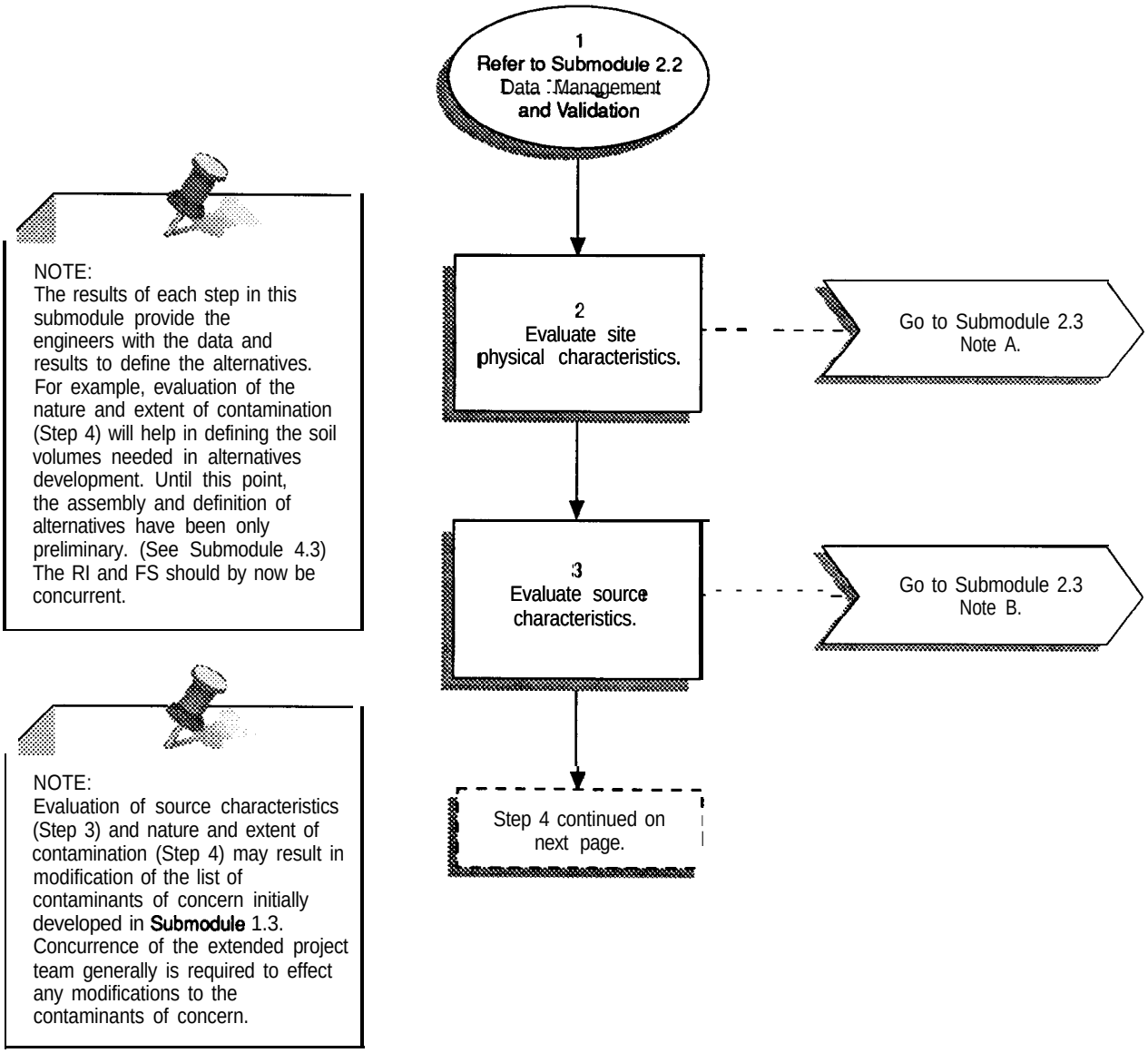
7. U.S. EPA, December 1991, *Risk Assessment Guidance for Superfund: Volume 1 –Human Health Evaluation Manual (Part B, Development of Risk-Based Preliminary Remediation Goals)*, Interim, OSWER Directive 9285.7-01B.

Submodule 2.3 Data Evaluation



Step 1. Refer to Submodule 2.2, Data Management and Validation.

Step 2. **Evaluate site physical characteristics.** Types of physical data commonly collected in RIs are listed in Submodule 2.3, Note A. Physical factors of the site generally include topography, geology, hydrogeology, surface water features, groundwater and surface water interactions, and meteorology. To the extent that data needs in these categories were identified during scoping, data evaluation will now be required for those data that were collected. Data evaluation activities include:

- Examining the data
- Developing summaries and presentations of the data using text, maps, conceptual drawings, graphs, or tables. This work results in essential materials that can be used directly in the RI report.
- Reviewing the summaries and presentation of the data to identify inconsistencies and/or unexpected results (e.g., outliers).

The results of this first step of data evaluation are used to confirm and refine the physical characteristic elements of the conceptual site model that were developed during scoping (e.g., soil types, aquifer boundaries and characteristics). Physical characteristics are important to understanding contaminant migration pathways and exposure pathways.

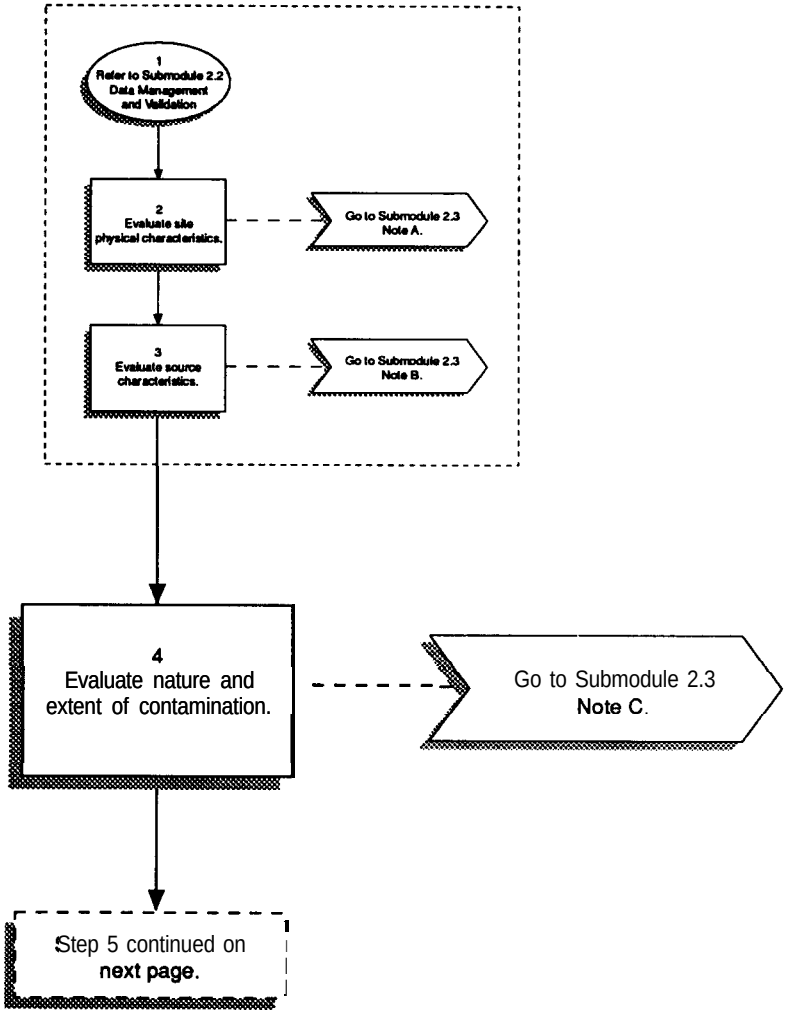
Note the necessity to review the DQOs established for the physical data elements and the decisions that the data were to support. Data collected during the RI frequently render some of the decisions and, therefore, DQOs obsolete or invalid. Examples of the types of situations that may be encountered are as follows:

- The conceptual site model included a hypothetical groundwater and surface water interaction. An investigation trench dug during the RI showed that no significant interaction was occurring. This eliminated a transport pathway and eliminated certain potential DQOs addressing surface water contamination.
- The conceptual site model hypothesized that a clay unit, which would block migration of contaminants toward the water table, underlies the surface impoundments. Drilling results detected a massive clay layer and thus confirmed this part of the conceptual model.

Step 3. **Evaluate source characteristics.** Sources could include tanks, pipes, trenches, buildings, outfalls, contaminated soils, landfills, ponds, sumps, piles, sediments, storage areas, equipment, and operations areas. Information collected during the RI about the sources at an OU includes the following:

- Facility characteristics, including numbers, locations, construction details, discharge points, historical information, surface features, and integrity of containment features
- Waste characteristics, including types, quantities, and chemical, radiological, and physical properties

Submodule 2.3 Data Evaluation (cont.)



Further detail on the collection of source data can be found in Submodule 2.3, Note B. The DQOs specified the critical characteristics of the sources for the investigation. Presentations of the details of the sources can include maps, drawings, text, and tables. The organization and presentation of the source characteristics are used directly in the RI report.

The site conceptual model is determined in part by the characteristics and history of the sources. Any changes in understanding of the sources must be reflected in the revised conceptual model. Examples include identification of new source terms, potential sources not confirmed in the field, new waste types, revised location and/or dimensions of sources, and changes in construed features.

Some data needs regarding sources tend to be binary issues (e.g., whether the source is in the expected location). Decisions for sources and, therefore, DQOs generally do not involve relative levels of quality or quantity of data. If the questions regarding sources in the work plan are answered, the DQOs have been met.

Step 4. **Evaluate nature and extent of contamination.** In many instances, the majority of the data collected during a remedial investigation addresses nature and extent of contamination. Typical categories of contamination information are groundwater, soils and vadose zone, surface water, sediments, air, and biota. Organization and development of information about contamination often requires considerable effort. Understanding the significance of the data is difficult without clear, adequate summary tables and figures. Such understanding may be especially difficult to communicate, often because of the amount of data involved. Geographical information systems, drawings, maps, isopleths, plots and graphs, tables, and text can all be used in evaluating the data and in developing an understanding of its significance, and ultimately in conveying that understanding.

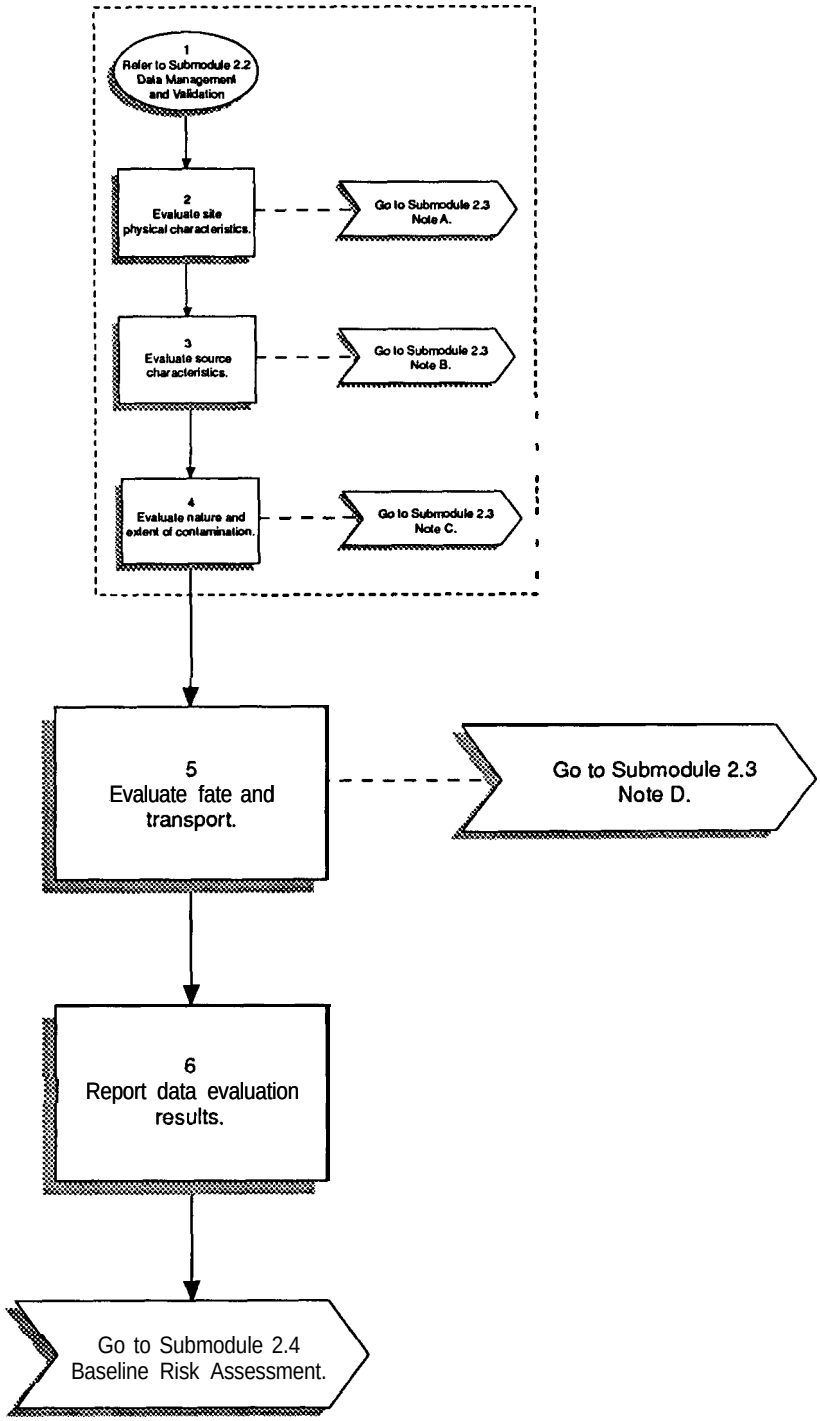
Nature and extent of contamination data have three major uses:

- To support the risk assessment (e.g., contaminant concentrations, spatial distributions and variability, and pathways)
- To support ARARs evaluations [e.g., RCRA hazardous waste status, exceedances of Maximum Contaminant Levels (MCLs)]
- To support technology evaluations (e.g., waste and/or soil characteristics, contamination levels, volumes of wastes and/or contaminated soils, geochemistry, and physical and chemical characteristics of the contaminants)

Examples of typical information needed to support these three purposes are given in Submodule 2.3, Note C.

Data that reflect the nature and extent of contamination provide a major opportunity to confirm and refine the conceptual site model. The investigation results confirm or modify the model to the extent that the model predicts where contamination should have been detected in the RI. Valid investigation results that cannot be explained on the basis of the conceptual model imply that modifications to the model might be needed. When this step of data evaluation is complete, the conceptual site model should be the best possible

Submodule 2.3 Data Evaluation (cont.)



explanation of all that is known about the site, including the ability to explain all of the contamination information collected during the RI.

Finally, determinations must be made regarding review of the DQOs established for the contamination data:

- Whether the DQOs, as originally formulated, remain valid for the site problems, as they are now understood
- Whether the DQOs have been met or whether significant data needs (either original or newly identified) remain

At many sites, the majority of the decisions and, therefore, the DQOs address contamination data. Agreement should be reached within the extended project team that the data needs have been met and that the quality of the data will support the risk assessment, ARARs evaluations, and development and evaluation of remedial alternatives. Further progress with the risk assessment is possible only when this consensus has been reached.

Step 5. **Evaluate fate and transport.** Evaluation of fate and transport primarily consists of using the physical characteristics, and source and contamination data already evaluated to project fate and transport of contaminants. This is necessary because the baseline risk assessment requires analysis of future and current risks. The primary tools are analytical and numerical models that are based on the revised and confirmed conceptual site model. However, this analysis should start with simple bounding calculations to assess whether conditions require more sophisticated modeling. The fate and transport modeling results will be presented in a manner similar to the other evaluation results. Submodule 2.3, Note D, provides further information on evaluating fate and transport.

Step 6. **Report data evaluation results.** A Site Characterization Summary Report (SCSR) is a technical memorandum (generally 10 pages or less) written to provide an initial evaluation of the data before completion of the final evaluation and the risk assessment. This allows an exchange of information with other agencies and a reference for initial review of the FS results, such as the alternatives development. The SCSR also provides information to enable the Agency for Toxic Substances and Disease Registry (ATSDR) to begin the health assessment and to enable the support agencies (Federal and State) to identify ARARs. Production of a SCSR is not required and may not be practical on a single-phase project with a short schedule; it is most useful for documenting data evaluation results on more complex OUs.

The SCSR should describe the site features briefly, although enough information should be included to allow the further identification of chemical- and location-specific ARARs. Available information should be summarized about the characteristics of the site contamination. A listing should be provided of contaminants, affected media, and probable concentrations. A complete definition of the contamination with regard to probable conditions and reasonable deviations is not expected at this stage. A final section of the SCSR may assess the sufficiency and uncertainties of the data and, if warranted, recommend further data collection.

Note A: Physical Characteristics

Information Needed	Purpose or Rationale	Collection Methods	
		Primary	Secondary
Vadose Zone Characteristics Permeability, variability, porosity, moisture content, chemical characteristics	Determine potential for in situ treatment	Existing literature	Water budget with soil moisture accounting Methods based on estimating or measuring hydraulic conductivity using: • Laboratory parameters • Relationships between hydraulics conductivity and grain size • Catalog of hydraulic properties • Field measurements of hydraulic conductivity using single or multiple wells
Drainage Patterns Overland flow, topography, channel flow pattern, tributary relationships, soil erosions, and sediment transport and deposition	Determine potential collection points	Topographic maps, site inspection, and soil conservation services	Aerial mapping and ground survey
Surface Water Bodies Flow, stream widths and depths, channel elevations, flooding tendencies, and physical dimensions of surface water impoundments	Determine volume and flows for containment RAs	Public agency data and atlases; catalogs, maps, and handbooks for background data	Aerial mapping and ground survey
Surface Water and Groundwater Relationships	Predict contaminant pathways for interceptive RAs	Public agency reports and surveys	Water level measurements or modeling
Groundwater Occurrence Aquifer's ability to transmit water	Determine potential quantities and rates for treatment options	• Existing literature Relations between hydraulic conductivity and grain size • Lab measurements of hydraulic conductivity • Thickness and depths of geologic units	• Groundwater level measurements (over time to monitor seasonal variations) • Measurements of hydraulic conductivity - Slug tests - Pumping and injection tests on monitor wells • Measurements of hydraulic gradients
Groundwater Recharge and Discharge Location of recharge and discharge areas	Determine interception points for withdrawal options or areas of capping	Existing site data, hydrologic literature, site inspection	Comparison of water levels in observation wells, piezometers, lakes, and streams Field mapping of groundwater recharge areas (losing streams, interstream areas) and groundwater discharge to surface water (gaining streams, seeps, and springs)
Rate	Determine variability of loading to treatment options	Existing literature	Water-balance calculations aided by geology and soil data

Note A.

Physical Characteristics. The physical characteristics of the site influence which remedial technologies and alternatives are appropriate for implementation. For example, the subsurface conditions, such as depth to impervious formations or the degree of fracture in bedrock, can limit the applicable types of containment and groundwater collection technologies. Information about the site's physical characteristics supports the conceptual development of remedial alternatives. The Note A graphic discusses the types of information typically used during the FS regarding the physical characteristics of the site.

Probable surface features and their uncertainties can be determined using aerial photography, surveying and mapping, and site inspection. Inspection of the site and the surrounding areas is normally augmented with photographs. Section 14 of the *Compendium* presents details on land surveying, aerial photography, and mapping.

The probable site physiography, geomorphology, and stratigraphy, as well as their uncertainties should be described. The investigation of site geology should be tailored to identify the features that will affect the fate and transport of contaminants or the implementability of one or more remedial technologies. For example, an understanding of site geology is less important at a site where release of contaminants occurs by volatilization rather than through leaching.

The site hydrogeologic model (a part of the site conceptual model) and its uncertainties should be described by identifying geologic characteristics, hydraulic properties, and groundwater use as follows:

Geologic Aspects

- Type and extent of water-bearing unit or aquifer (overburden, bedrock)
- Presence or absence of impermeable units or confining layers, their thickness, and permeability and leakance
- Depths to water table; thickness of vadose zone

Hydraulic Aspects

- Hydraulic properties and characteristics of all water-bearing units or aquifers
- Groundwater and surface water interactions; areas of groundwater discharge to surface water
- Seasonal variations of groundwater conditions

Groundwater Use Aspects

- Existing or potential aquifers as drinking water supply
- Existing near-site use of groundwater

Probable surface water features and their uncertainties, including erosion patterns and surface water bodies (such as ditches, streams, ponds, and lakes) should be described.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If potential pathways include surface water, information pertinent to contaminant transport may include physical dimensions, residence times of water, and flow rates.

Meteorological data should be presented–those data used to characterize the probable atmospheric transport of contaminants for risk assessment determinations and to characterize rainfall and evapotranspiration for assessing probable surface water runoff and percolation rates.

The probable ecological resources and uncertainties of the site and surrounding areas should be described. Information should include a general identification of the flora and fauna on and around the site, with particular emphasis on identifying sensitive environments, especially endangered species and their habitats and those species consumed by humans. Examples of sensitive environments include wetlands, floodplains, wildlife refuges, and specially designated areas such as scenic rivers or parks.

Depending on the specific circumstances, data may be collected for species that have key ecological functions in particular ecosystems, such as primary and secondary producers, decomposers, or predators. Bioaccumulation data on food chain organisms, such as aquatic invertebrates and fish, may be particularly important to ecological risk. Data gathered through biological assessment techniques (e.g., bioassays and field monitoring) may be useful in situations that involve complex mixtures, incomplete toxicity information, and/or unidentified or unmeasured compounds.

Note B: Source Characteristics

Information Needed	Purpose or Rationale	Collection Methods	
		Primary	Secondary[a]
Facility Characteristics:			
Source location	Locate aboveground and subsurface contaminant sources	Site inspection facility records, archival photos	Remote sensing, sampling, and analysis
Type of waste/chemical containment	Determine potential remedies for releases	Site inspection	Remote sensing, geophysics
Integrity of waste/chemical containment	Determine probability of release, timing of response, and use of existing containment	Site inspection	Sampling and analysis; nondestructive testing
Drainage control	Determine probability of release to surface water and collection points	Site inspection; topographic maps	
Engineered structures, utilities	Identify possible conduits for migration or interference with RAs	Site inspection; facility records	Remote sensing, geophysics
Site security	Determine potential for exposure by direct contact	Site inspection	
Known discharge points (outfalls, stacks)	Determine points of accidental or intentional discharge, collection points	Site inspection; facility records	
Waste Characteristics:			
Type	Determine contaminants for exposure assessments and treatment options	Site inspection; waste manifests	Sampling and analysis
Quantities	Determine magnitude of potential releases, volumes of material to be remediated	Site inspection	Sampling and analysis; geophysical surveys
Chemical, radiological, and physical properties	Determine environmental mobility, persistence, decay, and effects; determine parameters for development and evaluation of alternatives	Site inspection, handbooks, CHEMTREC/OHMTA DS, Chemical Information Service (CIS), and facility records	Sampling and analysis
Concentrations	Determine quantities and concentrations potentially released to environmental pathways	Site inspection	Sampling and analysis

[a]May be appropriate if detailed information would define risks otherwise apparent or, if resulting from a lack of published data, it is the only method.

Note B.

Source Characteristics. The characteristics of the facility, including prior waste management operations and disposal records, are described in Chapter 1 of the RI/FS Work Plan. Additional information about location, physical characteristics, and nature of contamination is attainable during the RI. Previous descriptions of these sources should be reviewed and updated to reflect this information. Sources of contamination are often hazardous substances contained in drums, tanks, surface impoundments, waste piles, landfills, intentional and unintentional release points (e.g., sumps and leaking pipes), and contaminated soils and sediments resulting from leaks and spills. All new information on source characteristics and source operating history should be analyzed to describe the source location and the type and integrity of any containment features.

Data on the physical characteristics of the sources are needed to provide engineering information for developing and evaluating the remedial alternatives. The location and the extent of sources possibly may be determined by nonchemical analyses; methodologies for this determination, which are described in Section 8 of the *Compendium*, include geophysical surveys and radiation walkovers. A variety of survey techniques [e.g., ground-penetrating radar, electrical resistivity, electromagnetic induction, magnetometry, and Geiger-Müller (GM) surveys] may detect and map the location and extent of buried waste material. The Note B graphic presents information about facility characteristics that are most often necessary to support the risk assessment and FS.

The probable characteristics should be described for the waste and its uncertainties, including the types, quantities, chemical properties, radiological properties, and physical properties. The Note B graphic illustrates some of the types of information that can be collected about a source.

Note C: Nature and Extent of Contamination

Example Technologies	Example Data Need
Waste/Soil Treatment Technologies	
Thermal Destruction	
Solids	Moisture Content Btu Heat Value Chlorine Content
Liquids	Particle Size Distribution Btu Heat Value Metal Concentrations
Solidification/Stabilization (Radiological/Mixed Waste Suitable)	Organic Content (TOC) Particle Size Distribution Moisture Content Atterberg Limits Radiological Constituents
Soil Vapor Extraction	Soil Type Particle Size Distribution VOC Concentration Soil Gas and Soil Matrix Soil Permeability Gas Permeability Moisture Content
Chemical Dehalogenation	Moisture Content TOC Concentration Particle Size Distribution Presence of Other Organics
Groundwater Treatment Technologies	
Air Stripping	VOC Concentration Henry's Law Coefficients TSS Inorganic Concentrations
Carbon Adsorption	TOC, COD, TSS Organic Concentrations
Oxidation	TOC, COD Cation/Anion Balance Alkalinity Organic Concentrations
Biological Treatment	BOD_5, TOC, COD Toxic Analyses
Precipitation	TDS pH Alkalinity, Hardness Cation/Anion Balance

Note C. **Nature and Extent of Contamination.** Sufficient information on nature and extent must be gathered to support technology evaluation, baseline risk assessment, and ARARs determination. Collected data should be evaluated against the output of the DQO process (i.e., data gap, data use, data need, decision rule) that is documented in the data collection plan.

Examples of data needs for nature and extent that are required to support technology evaluation are provided in the adjacent Note C graphic. Discussion of data needs for nature and extent to support baseline risk assessment is available in RAGS Part A, Chapters 4 and 5 (EPA, 1989).

Example of data needs for nature and extent to support ARARs determination could include the following:

Example ARARs Issue	Example Data Need
RCRA listed waste	Waste generating process information Toxicity Characteristic Leaching Procedure (TCLP)
Toxic Substances Control Act (TSCA)	Polychlorinated biphenyl (PCB) concentration
Clean Water Act (CWA) regulated contaminants	Contaminants concentration
Clean Air Act (CAA) regulated pollutants	Contaminants concentration


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Note D. **Fate and Transport of Contamination.** Additional information on determining contaminant fate and transport is provided in the *Superfund Exposure Assessment Manual* (EPA, 1988).

Subsurface. Contaminant fate and transport in the subsurface depends on the site physical characteristics, source characteristics, contaminant chemistry, and extent of contamination.

Analysis of subsurface fate and transport may be assisted with analytical or numerical modeling. Models can extrapolate between sampling points or into the future. Simplified analytical models can quantitatively estimate site conditions, but with lower accuracy and resolution than more detailed numerical models, which can account for more site-specific information. However, considerable uncertainty is associated with the use of models and that uncertainty must be noted when evaluating results.

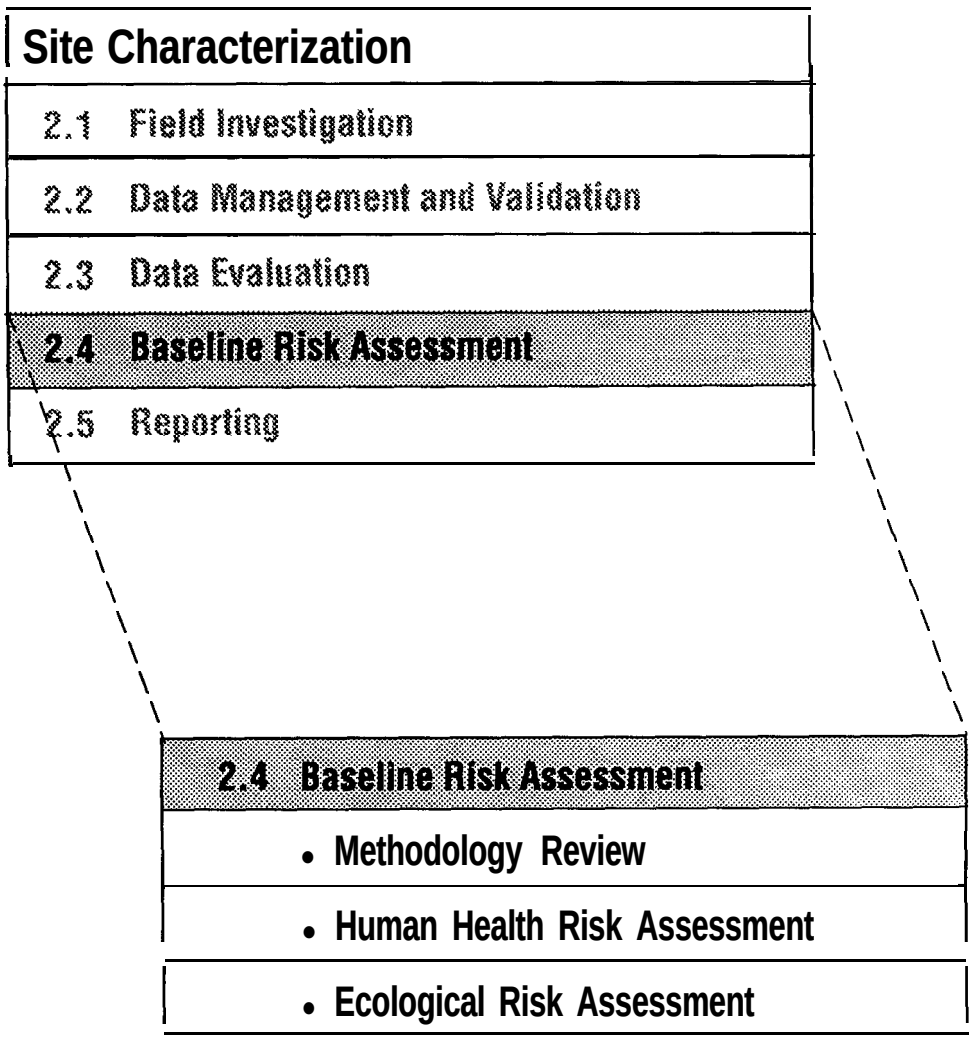
The fate and transport of contaminants in the groundwater will influence the effectiveness of the potential recovery system in terms of flows and capture zones, and may influence the effectiveness of the potential treatment system because the concentrations of parameters may vary, depending on their fate. Modeling efforts may be useful in supplementing understanding of the interrelationships of site conditions. In addition to providing specific characterization information, data from pump tests, slug tests, and/or pilot-scale recovery systems also may be used to support modeling efforts. Data should be collected only to fill specific identified data needs: data should not be collected to support modeling unless it fills specific data needs. Modeling efforts are always approximate; results should be used as approximations, not as absolutes.

Surface. Surface fate and transport should also be evaluated. Contaminants in surface water have three possible modes of transport: (1) sorption onto the sediment carried by the flow, (2) transport as a suspended solid, and (3) transport as a solute (dissolved). The transport of dissolved contaminants, which move the fastest, can be evaluated by characterizing the flow of the surface water and the contaminant dispersion. Sediment and suspended solid transport involve other processes such as deposition and resuspension.

As with soil, the consideration of fate and transport of contaminants in sediments is used in evaluating the effectiveness of potential alternatives. Anticipated resuspension of sediments during remediation may affect the short-term protectiveness of the alternative. Transport through the surface-water system will affect the extent of present or future releases.

Surface fate and transport information is also collected for the risk assessment. Fate of contaminants as they move through the food chain is important in assessing risks to ecological receptors. Bioaccumulation of contaminants is frequently a primary concern. Contaminants in the air exist as a gas or as particles. Radionuclide gases may decay to daughter products before dispersing, thereby changing the nature of the gas. Particles eventually deposit at some distance away from the site, but could be resuspended. In many instances, soil sampling results can be used in air transport models to assess potential impacts to air from particles or from volatiles in the soil.

Submodule 2.4 Baseline Risk Assessment



Submodule 2.4 Baseline Risk Assessment

Background

The NCP (55 FR 8665-8865, March 8, 1990) calls for a site-specific baseline risk assessment to be conducted as part of the RI. Specifically, the NCP states that the baseline risk assessment should "characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to groundwater or surface water, releasing to air, leaching through soil, remaining in the soil, and bioaccumulating in the food chain" (Section 300.430(d)(4)). The primary purpose of the baseline risk assessment is to provide risk managers with an understanding of the actual and potential risks to human health and the environment posed by the site, assuming no further Remedial Actions, and any uncertainties associated with the assessment. This information is used in determining the existence of a current or potential threat to human health or the environment that warrants Remedial Action, as well as in evaluating risk reduction effectiveness of remedial alternatives.

Organization

Submodule 2.4 discusses the following:

- Methodology review
- Human health risk assessment
- Ecological risk assessment

In addition, more detailed information is provided in the following notes:

- Note A–Human Health Risk Assessment
- Note B–Ecological Risk Assessment
- Note C–Land Uses and Exposure Scenarios

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4. U.S. EPA, September 1986, *Environmental Protection Agency Guidelines for the Health Risk Assessment of Chemical Mixtures,* Office of Health and Environmental Assessment, EPA/600/8-87/045.

5. U.S. EPA, April 1988, *Superfund Exposure Assessment Manual*, EPA/540/1-88/001, OSWER Directive 9285.5-1.

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10. U.S. EPA, December 1989, *Risk Assessment Guidance for Superfund, Volume I–Human Health Evaluation Manual*, Part A, EPA/540/1-89/002.

11. U.S. EPA, September 1989, *Risk Assessment Methodology Environmental Impact Statement for NESHAPS Radionuclides: Background Information Document, Volume 1*, EPA/520/1-89-005.

12. U.S. EPA, December 1991, *ECO Update: Ecological Assessment of Superfund Sites–An Overview*, Volume 1, Number 2, Office of Emergency and Remedial Response, Hazardous Site Evaluation Division, OSWER Directive 9345.0-05I.

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14. U.S. EPA, April 1991, *Role of Baseline Risk Assessment in Superfund Remedy Selection Decisions*, OSWER Directive 9355.0-30.

15. U.S. EPA, 1992, *Guidelines for Exposure Assessment*, Science Advisory Board, Washington, DC.

16. U.S. EPA, February 1992, *Framework for Ecological Risk Assessment*, Risk Assessment Forum, EPA/630/R-92-001.

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20. U.S. EPA, March 1992 (and supplements), *Health Effects Assessment Summary Tables (HEAST): Annual Update*, OSWER Directive 9200.6-303.

21. U.S. EPA, April 1992, *Guidance for Data Useability in Risk Assessment (Part A)*, OSWER Directive 9285.7-09A.

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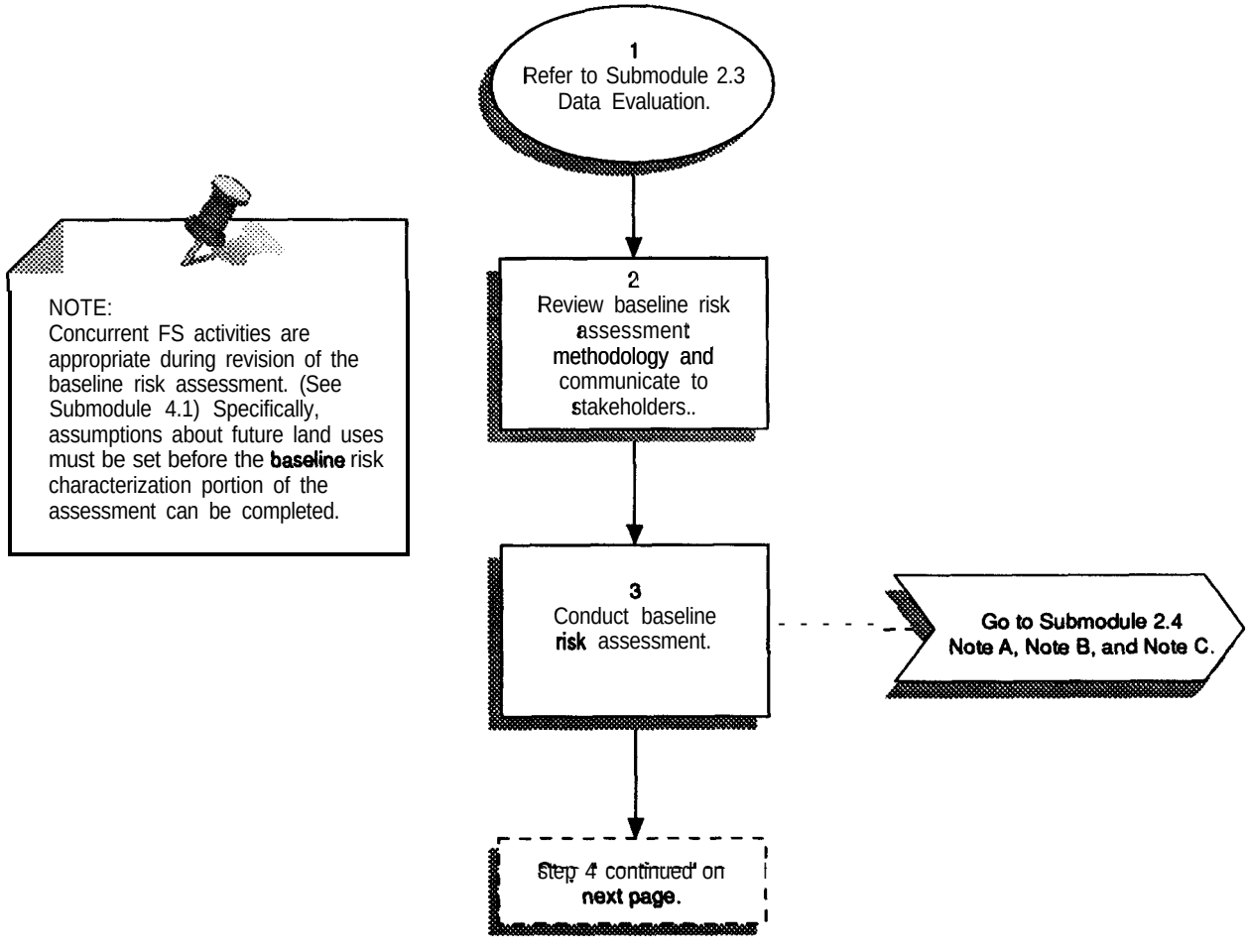
Submodule 2.4 Baseline Risk Assessment



Step 1. Refer to Submodule 2.3, Data Evaluation.

Step 2. **Review baseline risk assessment methodology and communicate to stakeholders.** Based on the results of data evaluation, including revision of the conceptual site model, another meeting with stakeholders is generally appropriate. The purpose of this meeting is (1) to present an updated view of the site's physical characteristics; sources, nature, and extent of contaminants; and fate and transport of contaminants and (2) to ensure that stakeholders concerns will be evaluated in the risk assessment (e.g., valued resources, special populations).

This stakeholder meeting is also an appropriate time to review and reaffirm the methodology that will be used to conduct the baseline risk assessment. A technical memorandum can be used to document changes in the methodology that result from this meeting. Prior to this stakeholder meeting, DOE should hold an internal and extended project team meeting to review the data and to identify any needed changes in the risk methodology. Typical changes in the risk assessment parameters are as follows:

Revisions to the list of contaminants of concern. Data collection can reveal fewer or additional contaminants at a site than originally were identified during Scoping (see Module 1). The list of contaminants requires careful screening before additions to the list of contaminants of concern. These screening techniques are described in Submodule 1.3, Initial Evaluation, and should be applied again at this stage. The number of contaminants listed as contaminants of concern directly affects the amount of data analysis required in the baseline risk assessment.

Changes in sources, pathways, and receptors. The data evaluation step often will identify changes to sources, pathways, or receptors. On the basis of modifications made to the conceptual site model, corresponding changes may be required in the risk assessment methodology.

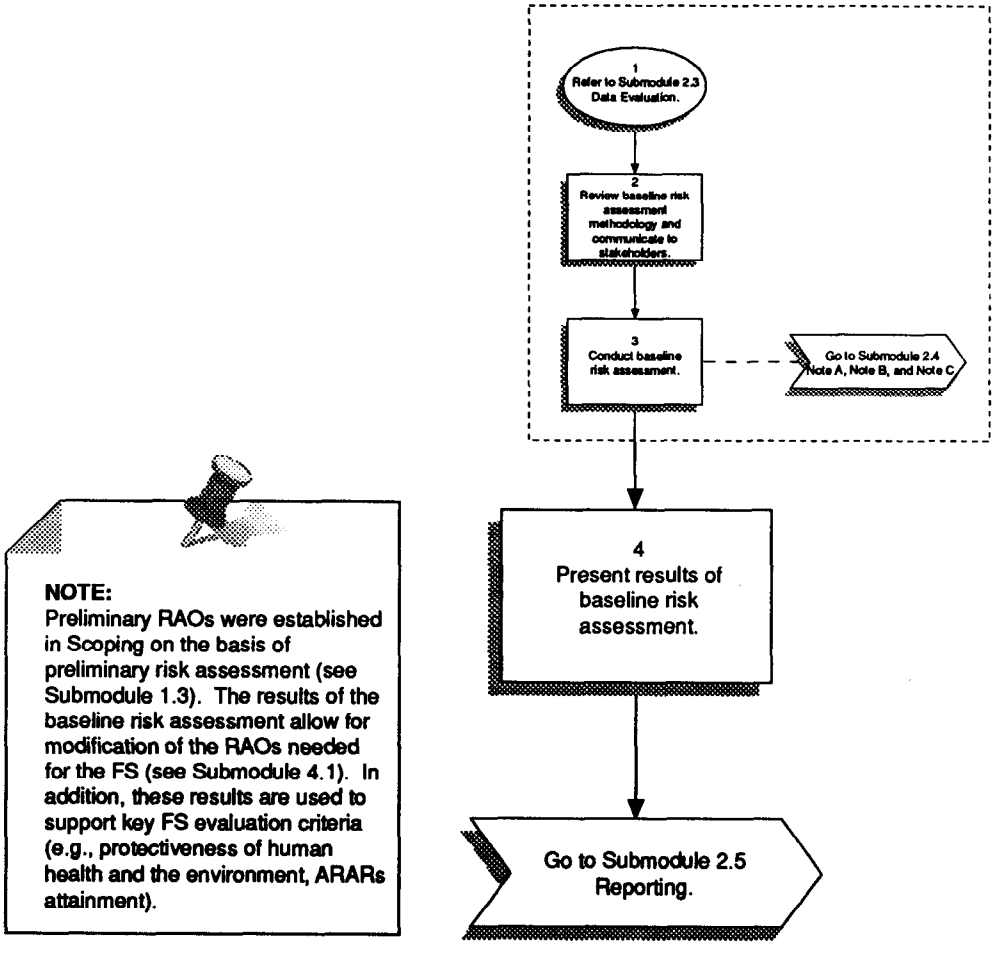
Revise remedial action objectives (RAOs). RAOs also may need revision to reflect the additional contaminants of concern that are now included in the baseline risk assessment, or to reflect changes in the sources, pathways, or receptors. In other situations, data evaluation may allow for the development of more specific and focused RAOs. For example, if an initial RAO was to "Meet ambient water quality criteria at compliance point X," it may now be appropriate to refine that RAO to include specific contaminants.

Step 3. **Conduct baseline risk assessment.** A baseline risk assessment includes human health and ecological components. EPA and other groups have written extensive guidance about how to conduct these assessments, although more information exists on conducting the human health assessment. Submodule 2.4, Notes A and B, provide information about elements of the baseline risk assessment. Submodule 2.4, Note C, describes the policy surrounding two major risk assessment issues: land use during the baseline assessment and formulation of reasonable maximum and average exposure scenarios.

Following are several issues that require attention as the assessments are conducted.

Use of databases. The risk assessment is one of the major steps where the data that were collected earlier will be used. All aspects of the baseline risk assessment require extensive data manipulation using statistical and spreadsheet software. If databases have not been

Submodule 2.4 Baseline Risk Assessment (cont.)



properly designed or data have not been entered carefully, the cost and schedule of the risk assessment can be overextended. Risk assessors should be involved in database design so that all of their data needs are addressed before this step.

Communication during risk assessment. Internal communication during the risk assessment is critical for ensuring that all appropriate members of the extended project team understand the methods used to develop risk estimates, the major assumptions, and how these methods and assumptions affect the risk characterization results. Communication with the other stakeholders is important to ensure understanding of the methodology and acceptance of the results.

Uncertainties are inherent in all risk assessments. These include uncertainties in the data, fate and transport models, risk assessment models, and the assumptions used in establishing estimates for exposure and toxicity. For all of its risk assessments, EPA directives require explicit documentation and explanation of the major uncertainties and assumptions. DOE risk assessors should follow this policy in the baseline risk assessment.

Qualitative and quantitative methods for handling uncertainties are available. The appropriate methods should be developed with the extended project team during Scoping (see Module 1). Note that some EPA regions now require quantitative analysis of uncertainty (e.g., Monte Carlo simulations).

Step 4. **Present results of baseline risk assessment.** Once the baseline risk assessment results are available and generally understood by the internal project team and the extended project team, they should be documented in a manner that will facilitate their communication to other stakeholders. These results generally will be presented using text, tables, and graphics, and will become a chapter in the RI report. In some instances, the results may be presented in a stand-alone report that is submitted to the stakeholders for review and comment.

Another meeting may be held to present and discuss the results of the risk assessment with the stakeholders. These results are important because they often receive such considerable attention that several meetings with different stakeholders may be required. This also is an appropriate point to reconsider the implications of the risk assessment results as compared with those obtained during Scoping (see Module 1). These results may directly indicate that certain remedial alternatives can affect risk reductions. For example, baseline risk results near acceptable risk levels (10^{-6} to 10^{-4} lifetime excess cancer risk for carcinogens, or a hazard index (HI) of 1 for non-cancer effects) may not be perceived to require extensive remediation. Regardless of the risk assessment results, other factors (e.g., location of a contaminant in a sensitive area) may indicate a need for extensive remediation.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Note A.

Human Health Risk Assessment. Risk determined for chemical and radiological scenarios will not be directly comparable. Exposure to background levels of radiation is unavoidable and can easily result in cancer risks of 10^{-4} to 10^{-3} (10^{-2} if radon is included); thus, a site with a radiological risk of 10^{-4} may not have contamination over background levels. Additionally, risk coefficients (slope factors) for radionuclides and chemicals have been determined using different methods. Radiological risk factors have been derived primarily from human data and represent "best estimates" (i.e., averages) of the true risk factors. Most chemical risk factors are derived from animal bioassay data extrapolated to humans, and the derived toxicity values represent the 95 percent upper confidence level of the mean value. Thus, chemical risk factors are usually biased high in comparison to the radiological risk factors. Radiological risks should be tabulated separately.

Contaminants of Concern. Contaminants of concern may be selected because of their intrinsic toxicological properties; because they are present in large quantities; because they presently are in or may move to critical exposure points associated with drinking water; or because they are persistent or may bioaccumulate. Chemical-specific ARARs may also identify contaminants of concern. Identification of contaminants of concern was begun during scoping and, as stressed in Module 1, is a critical step with potentially serious ramifications for the scope of the RI/FS. Every contaminant designated as a contaminant of concern will have to be considered throughout the entire risk assessment process to the final baseline risk assessment. *Contaminants of concern should be limited to those compounds that have a realistic potential of contributing significantly to risk.* This will control the magnitude and cost of the risk assessment and will focus the RI/FS on plausible concerns. RAGS Part A specifies requirements for establishing contaminants of concern. Submodule 1.3, Note C, also provides information on determining contaminants of concern.

Additional consideration should be given to identifying radiological contaminants of concern because of unique physical decay relationships. Daughter radionuclides may need to be added to the list of contaminants of concern because of decay processes. Transformation of chemicals in environmental degradation processes (e.g., formation of vinyl chloride) may also produce additional contaminants of concern.

Exposure Assessment. The conceptual site model is used to represent contaminant transport from the source to the receptor. Once the exposure pathways have been identified in the conceptual site model, the potential for exposure is assessed. Exposure scenarios are developed for known or expected receptor populations and based on current and future land use patterns. Exposure scenarios and assumptions should be agreed upon with the stakeholders. Individual EPA regions may have their own guidance on specific exposure scenarios and parameter values. Evaluation is done for any likelihood that identified pathways are significant contributors to exposure at the site. The amount of contaminated media that is contacted can be determined from actual receptors or may be estimated for current or future receptors. The potential for exposure is directly related to the current or future land use; a quantitative or qualitative estimate of the expected exposure is then made. Submodule 2.4, Note D, provides perspective on current DOE land use.


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Exposure is quantified by estimating the contaminant intake for the selected exposure scenarios. This estimate results in a dose or intake expressed in "amount of contaminant/kg of body weight/day." Direct exposure risks for radiation may be evaluated on the basis of results from soil samples or direct radiation measurements.

Toxicity Assessment. The toxicity assessment considers (1) the types of adverse health effects associated with acute and chronic exposures, (2) the relationship between the frequency and magnitude of exposure and adverse effects, and (3) related uncertainties such as the weight of evidence for a chemical's potential carcinogenicity in humans.

Radiologic-specific toxicity assessments are usually unnecessary because radiation dose (regardless of nuclide) directly relates to cancer. The most recent EPA *Health Effects Assessment Summary Tables* (HEAST) values for calculating cancer risk, and EPA Federal Guidance No. 11 should be used for calculating dose values. Use of older values may show that cancer mortality risks are greater than cancer incidence risks.

Risk Characterization. In the final component of the baseline risk assessment process, the potential health risks are characterized for each probable exposure scenario. Three risk numbers are developed for probable conditions: chemical non-carcinogenic risk, including radionuclides that have noncarcinogenic effects as metals (uranium as a kidney toxin); chemical carcinogenic risk; and radiological carcinogenic risk. Risks may also be calculated for reasonable deviations, thereby producing a range of risk numbers. The calculated risks should be compared with the calculated background risks. The results of the risk assessment may indicate that the site poses little or no threat to human health or that certain pathways are of no concern. Concurrent FS activities should be stopped if initial indications are that little or no actual or potential risks exist.


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Note B. **Ecological Risk Assessment.** EPA's Risk Assessment Forum (EPA, 1992) defined ecological risk assessment as a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. Ecological risk assessment consists of three main phases: (1) problem scoping, (2) analysis of exposures and effects, and (3) risk characterization. These phases must be integrated with the human health risk assessment to ensure cost-effective field sampling and analysis. The following principles can serve as useful guidelines when planning and conducting ecological risk assessments at DOE sites:

- A detailed ecological risk assessment during site characterization may not be necessary or appropriate for every site.
- Criteria, standards, or other measures for the protection of human health and welfare are not always protective of wildlife or ecological systems.
- An ecological risk assessment may require data in addition to that obtained for a human health risk assessment.
- Ecological consequences of remedial actions to protect human health need to be evaluated.

Because guidance on conducting ecological assessments is limited, the following steps are important:

- Assembling ecological risk assessment teams to include substantial biological and ecological expertise
- Involving appropriate natural resource trustees early in the planning process
- Contacting local and state fish and wildlife agencies for relevant background information

Available Guidance. Both EPA and DOE have published guidance on how to conduct ecological assessments at hazardous waste sites. EPA has published two primary guidance documents and a series of intermittent bulletins that describe the ecological risk assessment process for Superfund sites in general.

EPA's *Risk Assessment Guidance for Superfund: Volume II–Environmental Evaluation Manual* (EPA, 1989) describes the statutory and regulatory bases for ecological assessments in Superfund and basic concepts for understanding ecological effects of environmental contaminants. The document also reviews elements of planning an ecological assessment and provides guidance on how to organize and present results. The *Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference* (EPA, 1989) is a companion document that describes biological assessment strategies, field sampling designs, toxicity tests, biomarkers, biological field assessments, and data interpretation. The *ECO Update* intermittent bulletin series provides supplemental guidance on selected issues, including an overview of the process, coordination with natural resource trustees, and consultation with regional biological technical assistance groups. These guidance documents follow the EPA


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Risk Assessment Forum's general *Framework for Ecological Risk Assessment* (EPA, 1992).

DOE has published guidance on *Natural Resource Trusteeship and Ecological Evaluation for Environmental Restoration at Department of Energy Facilities* (DOE, 1991), which outlines DOE responsibilities as Federal natural resource trustees at DOE facilities and guidance relating to ecological evaluations under CERCLA and RCRA. This manual includes relevant Code of Federal Regulations (CFR) notices and a copy of RAGS, Volume II (EPA, 1989) as appendices.

EPA's (1992) approach to the baseline ecological risk assessment is similar to their approach to human health risk assessment and consists of three phases: (1) problem scoping, including characterizing the ecological setting, potential receptors, and end points of concern; (2) analysis of potential exposures and possible adverse effects; and (3) integrating information on exposure and effects to characterize risk and develop remedial action objectives (RAOs). An iterative or phased approach to data collection and analysis, with expert review of the results after each phase, can help streamline the process and minimize costs. DOE currently is developing guidance on work plans for the baseline ecological risk assessment (Draft Guidance–*Ecological Risk Assessment Guidance for Preparation of RI/FS Workplans*). Each of the three steps of EPA's (1992) approach is described below.

Problem Scoping. Problem formulation or scoping establishes the goals, breadth, and focus of the ecological risk assessment. The goal of this phase is a conceptual model of the site including the hypotheses that need to be tested with data from the site. At this stage, coordination with other natural resource trustees, risk assessment specialists, and stakeholders should begin. Problem scoping includes (1) characterizing the ecological setting and potential receptors; (2) qualitatively evaluating contaminant release, migration, and fate; (3) identifying contaminants of concern; (4) identifying exposure pathways; (5) identifying known ecological effects of the contaminants; (6) selecting assessment and measurement end points; and (7) developing a conceptual model for the site. Each of these steps is described below.

(1) The ecological setting and potential receptors step is key to focusing the risk assessment. This step requires one or more site visits by a trained biologist and includes describing and delineating the terrestrial, wetland, riparian, and aquatic habitats at the site; identifying species indicative of the healthy functioning of similar habitats (e.g., top-level carnivore, trout in cold water streams, naturally dominant vegetation, aquatic insect larvae); and identifying endangered or threatened species and other species protected under Federal or State law (e.g., Migratory Bird Treaty Act). It is not possible or necessary to evaluate all potentially exposed species and communities; instead, careful selection of assessment and measurement end points will result in the determination of appropriate indicator organisms, populations, and communities. The indicator organisms, populations, and communities will be the focus of the remainder of the risk assessment.

(2) Contaminant release, migration, and fate should be qualitatively evaluated in conjunction with the human health risk assessors. Several contaminant transport and fate mechanisms can have significant ecological consequences: aquatic


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sediments often serve as a sink for contaminants entering surface waters from overland runoff; groundwater can discharge contaminants to rivers, lakes, and ponds; and soils may sorb contaminants released to land. This step includes identifying sources that have released contaminants, identifying contaminant migration pathways, and identifying potential or actual areas of contamination.

(3) Contaminants of concern depend on intrinsic characteristics of the contaminant and on the amount of contaminant present. Relevant contaminant characteristics include their inherent toxicity to various groups of organisms; potential for bioaccumulation in food chains; bioavailability (i.e., presence in a form that can adversely affect organisms); tendency to spread in the environment; and types of toxic effects (e.g., lethal or sublethal responses). Measured or estimated contaminant concentrations in soils, surface waters, sediments, and biota (compared with background levels) and known areal extent of elevated contamination onsite and offsite help scope the potential ecological threats.

(4) Potential exposure pathways depend on the ecological setting and on characteristics and existing sources of contaminants. Significant ecological exposure pathways at hazardous waste sites may include direct contact with contaminated sediments (e.g., benthic aquatic communities); direct contact with contaminated surface waters (e.g., fish communities); ingestion of contaminated sediments (e.g., by demersal fish, benthic invertebrates); ingestion of contaminated aquatic plants or animals (e.g., by higher trophic level fish, waterfowl, fish-eating birds and mammals); ingestion of contaminated soils (e.g., by earthworms, burrowing mammals); ingestion of contaminated forage (e.g., by deer, domestic livestock); and ingestion of contaminated terrestrial prey (e.g., by hawks feeding on small mammals, woodcocks feeding on earthworms).

(5) Adverse ecological effects can be identified by reviewing ARARs and available scientific literature. For priority pollutants in aquatic ecosystems, state water quality standards or EPA Ambient Water Quality Criteria (AWQC) for the protection of aquatic life are chemical-specific ARARs for the protection of aquatic communities from a variety of adverse effects. Water quality criteria in some States may include in-situ assessments, which focus on the ecological health of aquatic communities and not on a substance-specific criterion. The DOE project manager or designee should identify such location-specific criteria early, particularly if a State considers such criteria to be an ARAR. For other contaminants and for other exposure media, potential adverse effects on different groups of organisms should be identified from the available literature. If available information is insufficient to characterize potential bioavailability and adverse effects, plans for how to proceed with site-specific investigations may be required (e.g., field surveys, toxicity tests, bioaccumulation studies):

- Toxicity tests evaluate the effects of contaminated media from the site on the survival, growth, reproduction, and metabolism of test organisms.

- Bioaccumulation potential, the tendency for chemicals to concentrate in tissues of living organisms, may be measured as the equilibrium ratio of the concentration of a chemical in the tissue to its concentration in an environmental medium (e.g., water). When the test organism is exposed


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through the medium only, the ratio obtained is the bioconcentration factor (BCF); when the organism is exposed both directly and through the food chain, the ratio is the bioaccumulation factor (BAF). EPA recommends that, if a contaminant is known or expected to bioconcentrate or bioaccumulate, tissue samples should be collected from biota at two or more trophic levels (e.g., plant, herbivore, carnivore) along with the surrounding media. These data are used directly to estimate exposure point concentrations for dietary exposures and indirectly to calculate site-specific BCFs or BAFs that can help predict food-chain transfer of contaminants to organisms at higher trophic levels.

- Field studies generally entail comparing measures from contaminated areas with measures from a reference area not affected by releases from the site.

(6) Assessment and measurement end points are key to developing RAOs. An assessment end point is any specific ecological value to be protected (e.g., a self-maintaining trout population in a stream). Assessment end points are used in decisionmaking to assess adverse ecological consequences. A measurement end point is a quantifiable characteristic related to an assessment end point (e.g., the chemical concentration in water that inhibits trout egg and fry development). A clear link must exist between the measurement end points and their respective assessment end points.

Examples of assessment end points include the following:

- A natural abundance and diversity of benthic community organisms
- Attainment of water quality standards associated with State-designated beneficial uses for the surface waters
- Adverse effects (e.g., on growth, reproduction, or survival) in federally designated endangered or threatened species or other protected species
- Disruption and simplification of aquatic communities, particularly in streams and lakes, reduced biodiversity, and loss of desired fisheries
- Contamination of wetlands and losses of fish and wildlife dependent on the wetlands
- Disruption of soil communities and loss of vegetation and habitat important for local biodiversity
- Bioaccumulation in terrestrial food chains, beginning with soil invertebrates or plant uptake of contaminants from soils

Examples of measurement end points include the following:

- Benthic invertebrate species abundance and diversity at the site compared with a reference area


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- The chemical concentration in sediments that kills benthic invertebrates
- Contaminant concentrations in surface water, sediments, and soils compared with background concentrations
- Measures of contaminant concentrations in organisms that represent successively higher trophic levels

Measurement end points may be redefined after initial scoping.

(7) The conceptual model for ecological effects at the site establishes the hypotheses that guide the work plan for field data collection. The conceptual model should include all significant contaminant sources, exposure pathways, exposure areas, and assessment and measurement end points. At this stage, sampling locations and DQOs can be developed for chemical and biological samples that will be required to establish baseline risks and to determine RAOs.

Analysis of Exposure and Effects. Once the work plan is established and the initial field sampling is complete, both measured parameters and predictive models can be used to estimate (1) exposures and (2) effects.

(1) The exposure assessment includes several steps as follows:

- Documenting contaminant release, migration, and fate
- Refining the description of ecological setting and receptors, including individuals of endangered or threatened species and populations, communities, and ecosystems of concern
- Refining assessment and measurement end points
- Estimating exposure concentrations based on measured values and models of fate and transport as necessary
- Characterizing the uncertainty in the assessment, including attainment of field DQOs, residual sampling uncertainty, fate and transport model uncertainty, and unmeasured potential natural variation in various parameters

(2) The ecological effects assessment also includes several steps as follows:

- Identifying relevant ARARs (e.g., AWQC)
- Documenting results from literature review and any field surveys or toxicity tests
- Based on the results, establishing the effect levels that are expected to have adverse consequences for the assessment end points (i.e., establishing ecological benchmarks). For example, the dose of a


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contaminant that might result in reproductive impairment in waterfowl might be estimated from the literature on the basis of toxicity tests using quail and mallard ducks

When establishing ecological benchmarks, the degree of "conservatism" should be specified for the appropriate end point of concern. If the analysis is a preliminary screen to focus assessment efforts or if the consequences of an effect are extreme, then no- or low-effect-levels might be used to establish benchmarks for comparison with the exposure assessment. When establishing RAOs, however, note that healthy populations usually can compensate for moderate losses, particularly at early life stages, and that relatively unstressed ecosystems also include functional and structural redundancies that allow them to tolerate some losses. However, already stressed populations and ecosystems may not tolerate further losses.

Risk Characterization. Models are used to integrate the results of the exposure assessment with results of the ecological effects assessment to estimate risks and characterize uncertainty. Contaminant concentrations in environmental media often are compared with ecological benchmarks using the quotient method (i.e., the ratio of a point estimate of an exposure concentration to a point estimate of an adverse effect level). A better estimate would be possible if probability distributions for both the exposure level and toxicity threshold were compared. If simultaneous exposures to more than one toxic substance is likely, the hazard index approach, which assumes additivity among toxic chemicals, provides an initial screen for risk [see RAGS Volume II, Chapter 8 (EPA, 1989)]. The implications of field surveys and toxicity tests also are incorporated. Finally, all sources of uncertainty and bias are described. If the uncertainty is too high to allow DOE to determine RAOs, the next step would be to investigate the types of additional data collection that could reduce uncertainties or systematic bias to the level required (e.g., sampling fish tissues to confirm aquatic food-chain contamination).


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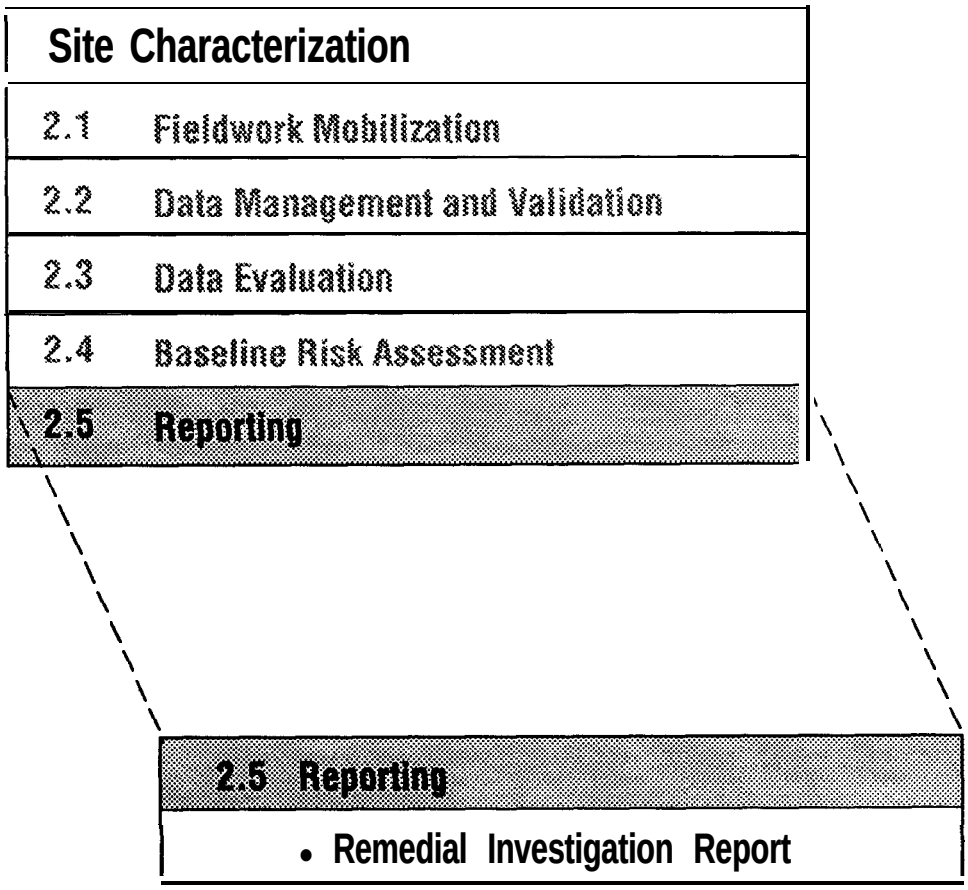
Note C. **Land Use and Exposure Scenarios.** The baseline risk assessment typically addresses several different exposure scenarios (residential, commercial/industrial, agricultural, recreational, intruder), with current and future land uses, presuming unrestricted use under the no-action scenario. The residential scenario usually presents the highest risks because it assumes continuous daily exposure for as many as 30 years, whereas an industrial scenario might assume exposure for 8 hours per day, 250 days per year, for 25 years. The differences in exposure conditions may have significant impact on the risk management decision of whether the site needs remediation (i.e., meets target risk criteria).

The determination of probable future land use at a DOE facility is difficult. DOE facilities may be isolated from population centers, security is currently extensive, and they are more similar to industrial facilities than are residential areas. Uncertainty may also exist about the facility's future mission. Given a facility's current location or future mission, inclusion of the residential scenario may seem unreasonable. EPA guidance notes that the assumption of "future residential land use may not be justifiable if the probability that the site will support residential use in the future is exceedingly small." An explicit DOE policy on how land use should be factored into the baseline assessment and the remedy selection process is not currently available. DOE project managers or the designee need to negotiate the appropriate land use assumptions with the other stakeholders. The baseline assessment should evaluate the likelihood of different future use alternatives, and should be discussed among the stakeholders during development of the risk assessment methodology. A range of scenarios probably will be most appropriate for the baseline assessment, but inclusion of a specific scenario in the baseline risk assessment does not dictate that the risk management decision must provide remediation to support that land use.

For all exposure scenarios, EPA policy requires the use of reasonable maximum exposure (RME) conditions–the "highest exposure reasonably expected to occur at a site." RME conditions result in an "exposure assessment that is conservative, but within a realistic range of exposure." To provide information on the uncertainties of exposures, EPA policy recently has been modified to require the addition of scenarios for consideration of average exposure conditions. EPA has not yet issued guidance on the exposure parameter values to use in average exposure scenarios, although the probable conditions as identified in the conceptual model should be similar to the parameters used to determine exposure levels for the scenarios. EPA has stated that remedial decisions will continue to be made on the basis of the RME exposures.

Submodule 2.5 Reporting



Submodule 2.5 Reporting

Background

Writing the RI report should be relatively straightforward. Many of the sections have been prepared as technical memoranda (e.g., the SCSR) or other documents in Submodules 2.1, 2.2, 2.3, and 2.4.

Organization

Submodule 2.5 discusses the following:

- Remedial Investigation Report

In addition, more detailed information is provided in the following notes:

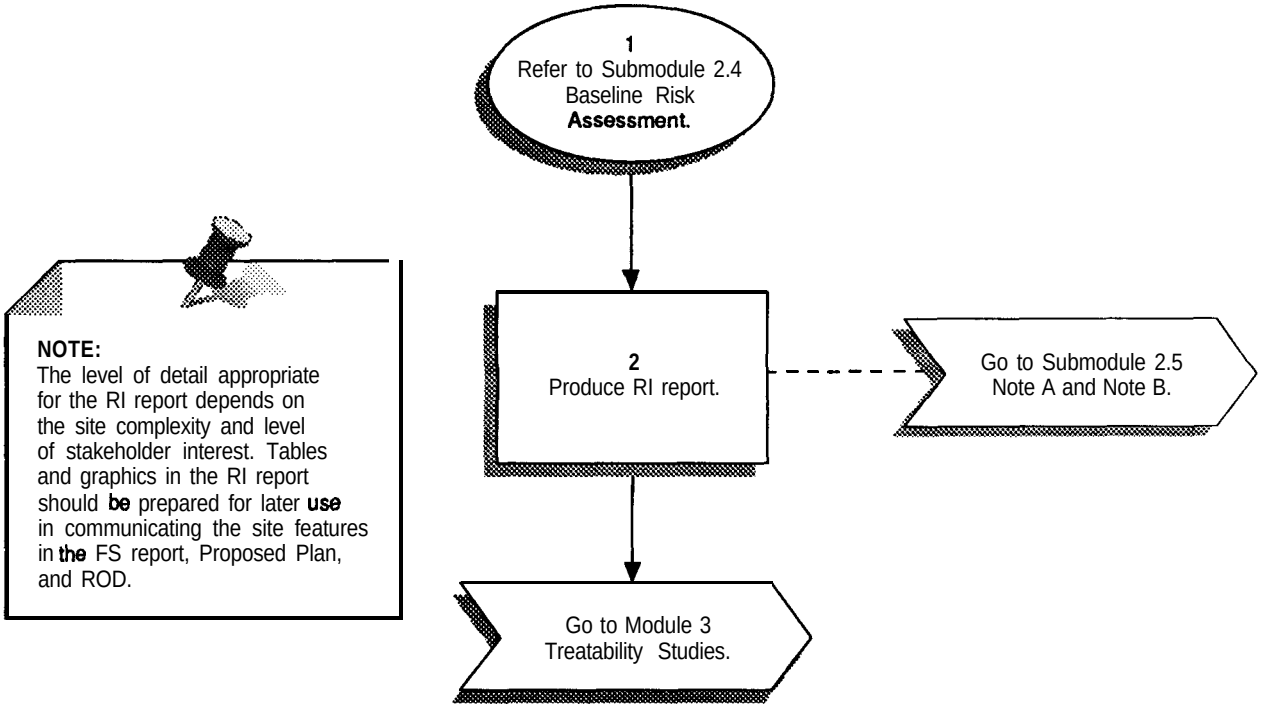
- Note A–Suggested RI Report Format
- Note B–Guidance on Documenting Risk Assessments

Sources

1. U.S. EPA, October 1988, *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA*, Interim Final, EPA/540/G89/004, OSWER Directive 9356.3-01.

2. U.S. EPA, February 1992, *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, Memorandum.

Submodule 2.5 Reporting



Step 1. Refer to Submodule 2.4, Baseline Risk Assessment.

Step 2. **Produce RI report**. The draft RI report is produced for review by the lead and support regulatory agencies and submitted to the ATSDR for use in preparing a health assessment. Compliance agreements and DOE policy statements also may specify who must review this report. The RI also documents data collection and analysis, including support of the FS. An example outline is presented in Submodule 2.5, Note A. This outline may be modified or another outline may be used if the pertinent issues are included. Some DOE facilities have standardized primary document outlines. The RI report (or executive summary) should be made available to the extended project team and other stakeholders, and should be the basis for a meeting if such interest is expressed.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Note A. **Suggested RI Report Format**.

Executive Summary

1. Introduction
   - 1.1 Purpose of Report
   - 1.2 Site Background
     - 1.2.1 Site Description
     - 1.2.2 Site History
     - 1.2.3 Previous Investigations
   - 1.3 Report Organization

2. Study Area Investigation
   - 2.1 Surface Features (natural and manmade, topographic mapping, etc.)
   - 2.2 Contaminant Source Investigations
   - 2.3 Meteorological Investigations
   - 2.4 Surface Water and Sediment Investigations
   - 2.5 Geological Investigations
   - 2.6 Soil and Vadose Zone Investigations
   - 2.7 Groundwater Investigations
   - 2.8 Radiological Walkovers
   - 2.9 Human Population Surveys
   - 2.10 Ecological Investigations

   If technical memoranda documenting field activities were prepared, they may be included in an appendix and summarized in this report chapter.

3. Physical Characteristics of the Study Area
   - 3.1 Surface Features
   - 3.2 Meteorology
   - 3.3 Surface Water Hydrology
   - 3.4 Geology
   - 3.5 Soils
   - 3.6 Hydrogeology
   - 3.7 Demography and Land Use
   - 3.8 Ecology

4. Nature and Extent of Contamination
   - 4.1 Results of Data Usability Evaluation
   - 4.2 Results of site characterization (natural components and contaminants in some, but not necessarily all, of the following media)
     - 4.2.1 Sources (lagoons, sludges, tanks, etc.)
     - 4.2.2 Soils and Vadose Zone
     - 4.2.3 Groundwater
     - 4.2.4 Surface Water and Sediments
     - 4.2.5 Air


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5. Contaminant Fate and Transport
   - 5.1 Potential Routes of Migration (air, groundwater, etc.)
   - 5.2 Contaminant Persistence
     - 5.2.1 Description of applicable (for organic constituents), estimated persistence in the study area environment and physical, chemical, and/or biological factors of importance for the media of interest
     - 5.2.2 Description of applicable radiological decay series
   - 5.3 Contaminant Migration
     - 5.3.1 Discussion of factors affecting contaminant migration for media of importance (sorption onto soils, solubility in water, movement of groundwater, etc.)
     - 5.3.2 Discussion of modeling methods and results, if applicable

6. Conceptual Site Model
   - 6.1 Sources
   - 6.2 Release Mechanisms
   - 6.3 Pathways
   - 6.4 Receptors

7. Risk Assessment
   - 7.1 Human Health Risk Assessment
     - 7.1.1 Exposure Assessment
     - 7.1.2 Toxicity Assessment
     - 7.1.3 Risk Characterization
   - 7.2 Environmental Risk Assessment

8. Preliminary Alternatives Development (Optional)
   - 8.1 Remedial Action Objectives
   - 8.2 Technology Screening
   - 8.3 Alternatives Development

9. Summary and Conclusions
   - 9.1 Summary
     - 9.1.1 Nature and Extent of Contamination
     - 9.1.2 Fate and Transport
     - 9.1.3 Risk Assessment
   - 9.2 Conclusions
     - 9.2.1 Data Limitations and Recommendations for Future Work
     - 9.2.2 Recommended Remedial Action Objectives

Appendices
- A. Technical Memorandums on Field Activities (if available)
- B. Analytical Data and QA/QC Evaluation Results
- C. Risk Assessment Methods


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Note B. **Guidance on Documenting Risk Assessments.**

EPA guidance provides valuable recommendations to risk assessors and others in documenting the results of risk assessments. EPA recommends that risk assessors "need to be completely candid in describing risks and in explaining regulatory decisions. Specifically, the Agency's risk assessment guidelines call for full and open discussion of uncertainties in the body of each . . . risk assessment, including prominent display of critical uncertainties in the risk characterization. Numerical risk estimates should always be accompanied by descriptive information carefully selected to ensure an objective and balanced characterization of risk in risk assessment reports."

The concept of "full and complete risk characterization" does not refer to an ideal assessment in which risk is completely defined by fully satisfactory scientific data. Rather, the concept of complete risk characterization means that information needed for informed evaluation and use of the assessment is carefully highlighted. Thus, even though risk characterization details limitations in an assessment, a balanced discussion of reliable conclusions and related uncertainties enhances, rather than detracts, from the overall credibility of each assessment."

Finally, "regarding exposure and risk characterization, it is [EPA] policy to present information on the range of exposures derived from exposure scenarios and on the use of multiple risk-descriptors (i.e., central tendency, high end of individual risk, population risk, important subgroups, if known). . ."

(From U.S. EPA, February 1992, *Guidance on Risk Characterization for Risk Managers and Risk Assessors*.)


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